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Informed Consent for All! No Exceptions

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INFORMED CONSENT FOR ALL! NO EXCEPTIONS

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I. INTRODUCTION

Less than 200 years ago, physicians were cautioned that "[y]our patient has no more right to all the truth you know than he has to all the medicine in your saddlebags....He should get only as much as is good for him."[1] Similarly, the American Medical Association's first code of ethics warned the physician "to avoid all things which have a tendency to discourage the patient and to depress his spirits."[2] Over time, however, these paternalistic viewpoints of the physician-patient relationship were replaced by a modern, patient-oriented approach that emphasized informed decision making by the patient.[3] Now, physicians give care under Justice Cardozo's view that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his [or her] own body."[4] This modern view forms the backbone of the doctrine of informed consent.[5] The doctrine has developed exceptions arising at common law and in federal and state statutes.[6] The doctrine and its exceptions continue to have a broad impact on both the practice of medicine and the evolution of society.[7]

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1. Ben A. Rich, *Prognostication in Clinical Medicine*, 23 J. LEGAL MED. 297, 317 (2002) (second alteration in original) (quoting Oliver Wendell Holmes, *The Young Practitioner*, *in* MEDICAL ESSAYS 1842–1882, 370, 388 (Classics Med. Library ed. 1987)).

2. W. John Thomas, *Informed Consent, the Placebo Effect, and the Revenge of Thomas Percival*, 22 J. LEGAL MED. 313, 315 (2001) (quoting CODE OF ETHICS (1847) art. I(4), *reprinted in* AMERICAN MEDICAL ETHICS REVOLUTION: HOW THE AMA'S CODE OF ETHICS HAS TRANSFORMED PHYSICIANS' RELATIONSHIPS TO PATIENTS, PROFESSIONALS, AND SOCIETY 324, 325 (Robert B. Baker et al. eds., 1999)). This first version of the 1847 code of ethics also "advised against allowing the patient any voice in diagnosis and treatment: '[Physicians should....unite in *tenderness* with *firmness*, and *condescension* with *authority*, as to inspire the minds of their patients with gratitude, respect and confidence].'" *Id.* (quoting CODE OF ETHICS (1847) art. I(1), *supra*, at 324) (internal quotation corrected).

3. *See* Rich, *supra* note 1, at 317; James A. Bulen, Jr., *Complementary and Alternative Medicine*, 24 J. LEGAL MED. 331, 337–38 (2003).

4. Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914), *abrogated on other grounds by* Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957), *and superseded by statute*, N.Y. PUB. HEALTH LAW § 2805-d(1) (McKinney 2002); *see also infra* Part II discussing *Schloendorff*. Although the case dates back to 1914, the seeds of the doctrine put forth in *Schloendorff* were sown as early as the 1700s. "[I]t is reasonable that a patient should be told what is about to be done to him...." Slater v. Baker & Stapleton, 95 Eng. Rep. 860, 862 (K.B. 1767). In *Slater*, a patient sued his two physicians for placing his broken leg in an experimental device designed to improve healing. *See* Madeleine M. Jester, *A History of Informed Consent*, RISK REVIEW (1998), http://www.cnahealthpro.com/amt/consent_history.html. The suit was brought not only on the grounds that the physicians were experimenting on him, but also that they had done so without his informed consent. *Id.*

The seeds of the informed consent doctrine continued to grow in the late nineteenth century: "To deliberately inject a poison of known high degree of virulency into a human being, unless you obtain that man's sanction...is criminal." Ezekiel Emmanuel, Nat'l Insts. of Health, *What Makes Clinical Research Ethical?* 2 (2005), http://bioethics.nih.gov/hsrc/slides/Zeke-Ethical_Research.pdf (quoting William Osler's 1898 response to an oral presentation by Giuseppe Sanarelli on the discovery of the agent for transmission of yellow fever).

5. *See* Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413, 414.

6. *See generally id.* (discussing the exceptions to informed consent).

7. *See id.* at 427–28.

Informed consent in the treatment context has a different purpose than in the research context, requiring a different level of protection and consent for the patient than for the research subject. Because there is a greater potential for harm in research, there must be greater protection for a research subject. With varying levels of protection, exceptions to the doctrine have been carved out to allow for situations when obtaining consent is impossible or not feasible. Recent advances in medical technology have brought the requirement of informed consent into stark relief. There is a rich literature on informed consent, so rather than providing a complete review, this Article examines the doctrine in the treatment and research contexts through the use of recent case law and clinical research trials. Part I describes the importance of informed consent and the different levels of protection necessary in the contexts of treatment and research. Part II briefly examines informed consent for treatment. Part III traces the history of informed consent for research and discusses the important distinction between therapeutic and nontherapeutic research. Part III also evaluates the role of researchers' economic interests as well as that of institutional review boards. Part IV analyzes exceptions to the informed consent doctrine, first in the treatment context, then in the research context. Finally, Part V concludes with a call for a re-evaluation of the informed consent process to squarely meet the growing sophistication in research methods. Specifically, this Article argues that the exceptions to informed consent in research should be abolished. With advances in genomic and genetic medicine, the potential development of additional exceptions to the doctrine of informed consent creates the risk of the exceptions swallowing the rule—that all individuals be accorded the opportunity to give their informed consent for participation in research trials or to receive treatment.

A. An Introduction to Informed Consent

Informed consent stems from the common law tort of battery[8] and requires that a caregiver or researcher not minister to or even touch a patient until the patient has received and agreed to some essential information about the proposed course of treatment.[9] This requirement imposes an affirmative duty on the caregiver or researcher.[10] The duty cannot be satisfied in one fell swoop—informed consent is an ongoing process and "not just *pro forma* adherence to checklists and forms."[11] It involves "ensuring...that a patient *truly understands* the parameters of a proposed treatment and agrees to accept treatment."[12]

Three basic components comprise a valid informed consent: capacity, disclosure, and voluntariness.[13] A patient must have the capacity to understand both the

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8. *E.g.*, GEORGE J. ANNAS, THE RIGHTS OF PATIENTS 115 (3d ed. 2004).
9. *E.g.*, *id.* at 113.
10. *E.g.*, *id.* at 115.
11. RONALD W. SCOTT, LEGAL ASPECTS OF DOCUMENTING PATIENT CARE 126 (1994).
12. *Id.* at 126–27 (emphasis added). This rigid adherence to the ongoing process comes notwithstanding the fact that a recent study of consents obtained in a cancer trial revealed ninety percent patient satisfaction with the informed consent process. *See* Martin H.N. Tattersall, *Examining Informed Consent to Cancer Clinical Trials*, 358 LANCET 1742 (2001).
13. Edward Etchells, *Informed Consent in Surgical Trials*, 23 WORLD J. SURGERY 1215, 1215 (1999); *see also* Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J. L. & MED. 361, 364–69 (2002). For a more detailed discussion of the elements of informed consent, see *infra* Part I.B. For a discussion of actual comprehension by the patient, an extension of capacity, see *infra* notes 201–206.

information presented and its relevance, and be able "to appreciate the reasonably foreseeable consequences of her decision."[14] In turn, the caregiver must disclose relevant information to the patient in terms that the patient can understand.[15] Finally, a patient's decision based on that information must be made voluntarily—"without force, coercion, or manipulation."[16] Each of those components must be present for a patient's consent to be valid.[17]

Courts use two different standards to evaluate the scope of information that physicians must disclose for consent to be informed: the physician-oriented standard and the patient-oriented standard.[18] The physician-oriented standard adopts the reasonable physician's viewpoint of what information should be disclosed, while the patient-oriented standard adopts the patient's viewpoint.[19] The patient-oriented viewpoint has gained acceptance, but the traditional, physician-oriented viewpoint is still the law in approximately half of the states.[20] However, a physician's duty to disclose relevant information must not be confused with his duty to follow the standard of care.[21] The duty to disclose and the duty to follow the standard of care are separate professional requirements.[22]

Informed consent is required when a patient receives treatment from her physician and when a researcher conducts a study involving human subjects.[23] "Treatment" is defined as "all the steps taken to effect a cure of an injury or disease, including examination and diagnoses as well as application of remedies."[24] "Research" is defined as an "investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[25] Two values guide informed consent in both treatment and research: self-

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14. *See* Etchells, *supra* note 13, at 1215. While Dr. Etchells' article focuses on surgical research trials, corollaries can easily be made to any context where informed consent is required. His article provides a list of questions that should be used to assess patient capacity relating to research participation, as well as the types of information that a patient should be provided regarding clinical trials. *Id.* at 1216.

15. *Id.* at 1215.

16. *Id.*

17. *Id.*

18. *See* Bulen, *supra* note 3, at 332.

19. *Id.*

20. *Id.* at 335–38.

21. *Id.* at 335. The case of *Canterbury v. Spence* created an objective legal standard by which physicians' disclosure activities should be judged. 464 F.2d 772 (D.C. Cir. 1972). "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves." *Id.* at 784. This holding effectively removed subjective viewpoints from the equation because it was neither the patient nor the physician who determined the information to be disclosed; rather, it was the law that determined which information was to be disclosed.

In this context, the "standard of care" may be defined as the conduct demanded of a reasonable physician in a given situation. *See* BLACK'S LAW DICTIONARY 1441 (8th ed. 2004).

22. *See* Bulen, *supra* note 3, at 335.

23. *See generally supra* notes 7, 13.

24. BLACK'S LAW DICTIONARY 1346 (5th ed. 1979).

25. 45 C.F.R. § 46.102(d) (2005). "Research" was defined in the Belmont Report as

> 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). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

Noah, *supra* note 13, at 387–88 (quoting 44 Fed. Reg. 23,192–93 (Apr. 18, 1979)).

determination and respect for persons.[26] The value of self-determination is inculcated in the doctrine by recognizing that a patient can only make an informed decision on her treatment if the physician discloses both the risks and the benefits of that treatment.[27] The value of respect for persons is most at risk in the research context because the individual might feel pressured to participate in research trials because she fears reduced care.[28]

Research studies require a higher standard of review for informed consent because of the increased risk of harm and lack of corresponding benefit to the subject by participation in the study.[29] The research subject requires a more thorough explanation of the details of the study than if she were simply receiving treatment, especially the study's potential harmful consequences. Researchers have recently pointed to an increased blurring of the distinction between the treatment and research viewpoints, which signals a movement toward a single standard of review for informed consent.[30]

At times it can be impossible to obtain informed consent from an individual. Rather than completely bar treatment or research in those situations, several exceptions to informed consent have been carved out. The most commonly recognized exceptions are (1) for the provision of care when the patient is incapacitated, such as in an emergency situation; (2) for therapeutic privilege in the treatment context; and (3) for patients' voluntary waiver of informed consent.[31] When an exception to informed consent applies, a caregiver or investigator is permitted to proceed despite a total or partial lack of a patient's informed consent.[32]

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26. *See, e.g.*, Timothy M. Banks, *Misusing Informed Consent: A Critique of Limitations on Research Subjects' Access to Genetic Research Results*, 63 SASK. L. REV. 539, 545 (2000).

27. *Cf. id.* at 546.

28. *See, e.g., id.*; Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 34 (1993). "[P]rospective research subjects may be open to subtle coercion due to a mistaken belief that their care may be affected by whether they participate in the research." Banks, *supra* note 26, at 546; *see also* Rich, *supra* note 1, at 322 ("The doctrine of informed consent is unequivocally a creature of law."). The doctrine was first recognized in 1947 during the Nuremberg trials and is discussed *infra* Part III.A.1. It was first used by a court in 1957 in *Salgo v. Leland Stanford Jr. University Board of Trustees*, 317 P.2d 170 (Cal. 1957).

29. *See* Noah, *supra* note 13, at 363; Sandra J. Carnahan, *Promoting Medical Research Without Sacrificing Patient Autonomy: Legal and Ethical Issues Raised by the Waiver of Informed Consent for Emergency Research*, 52 OKLA. L. REV. 565, 573 (1999).

30. *See* Noah, *supra* note 13, at 363.

> It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully designed....When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested, or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective.

Id. at 387–88 (quoting 44 Fed. Reg. 23,192–93 (Apr. 18, 1979)).

31. *See* Rich, *supra* note 1, at 329. For a detailed discussion of the three most commonly recognized exceptions, as well as an analysis of the "waiver" exception, see *infra* Part IV.

32. *E.g.*, Meisel, *supra* note 5, at 433. "The exceptions to the informed consent doctrine are as firmly rooted in the societal value accorded to health as the informed consent doctrine's dual requirements of disclosure and

B. The Importance of Informed Consent for Treatment

Informed consent in treatment is a right engendered by society that developed throughout the second half of the twentieth century.[33] This right pivots on four primary societal interests: "(1) the preservation of life; (2) the prevention of suicide; (3) the maintenance of the medical profession's ethical integrity; and (4) the protection of the interests of third parties."[34] These interests place responsibility for the patient and her treatment on the caregiver. The tension created by maintaining these values, while still respecting individual autonomy, makes informed consent crucial to the care patterns of physicians and the individual patient's treatment options. Through these societal interests, two affirmative duties flow to the caregivers:[35] the duty to disclose all relevant information to the patient[36] and the duty to obtain consent from the patient prior to commencing treatment.[37] These two duties shape the manner of treatment because, by having to disclose risks and obtain consent, physicians are forced to conform to the patient's subjective view of acceptable treatment. If a patient chooses to forego an existing available treatment, the physician must ensure that the patient understands the immediate and potential consequences to her health but must ultimately respect the patient's decision.

Oliver Wendell Holmes observed that "[t]here is nothing men will not do...to recover their health and save their lives."[38] This basic survival instinct is what makes informed consent important because a tension exists between the desire and the right of an individual to pursue treatment and the overall interests of society reflected in the social and economic costs of treatment. With patients often ready to try virtually anything and everything to save their lives or to improve their health, informed consent functions as a societal and ethical check on the behavior of patients and their caregivers.

There are six primary elements and one catch-all provision that most medical ethicists view as necessary for proper informed consent in the treatment context.[39] The caregiver must discuss the following in a manner that the patient can understand:

> (1) A description of the *recommended treatment* or procedure; (2) [a] description of the *risks and benefits* of the recommended procedure, with special emphasis on risks of death or serious bodily disability; (3) [a] description of the *alternatives*, including other treatments or procedures, together with the risks

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consent are in the societal value accorded to individualism." *Id.* However, if informed consent from the patient or subject is not obtained, and an exception does not apply, then the physician may be liable to the patient on a negligence theory if the patient is injured. *See* Bulen, *supra* note 3, at 331.

33. *See* Meisel, *supra* note 5, at 413.

34. Suzanne K. Ketler, Note, *The Rebirth of Informed Consent: A Cultural Analysis of the Informed Consent Doctrine After* Schreiber v. Physicians Insurance Co. of Wisconsin, 95 NW. U. L. REV. 1029, 1039 (2001); Elaine B. Krasik, Comment, *The Role of the Family in Medical Decisionmaking for Incompetent Adult Patients: A Historical Perspective and Case Analysis*, 48 U. PITT. L. REV. 539, 545 (1987).

35. *See* Meisel, *supra* note 5, at 486.

36. *Id.*; *see also* Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 844 (Md. 2001) ("A human subject is entitled to *all* material information.").

37. *E.g.*, Meisel, *supra* note 5, at 486.

38. ANNAS, *supra* note 8, at 1.

39. *Id.* at 86.

> and benefits of these alternatives; (4) [t]he likely results of *no treatment*; (5) [t]he *probability of success*, and what the physician means by success; (6) [t]he major problems anticipated in *recuperation*, and the time period during which the patient will not be able to resume his or her normal activities; and (7) [a]ny other information generally provided to patients in this situation by other qualified physicians.[40]

By describing the treatment and its alternatives, including the risk of no treatment, as well as success rates and potential problems, the patient is given a vivid picture of her situation.

Merely presenting the necessary information to the patient is insufficient to achieve informed consent. The caregiver must also ensure that each individual patient understands the information presented. This places a great deal of responsibility on the caregiver to make a subjective determination as to whether each patient understands the information. Commentators have suggested that a significant portion of the population does not have sufficient knowledge to give informed consent after a physician has presented the necessary information.[41] For example, a recent British study analyzed stroke victims' consent processes and revealed that thirty-nine percent of the patients surveyed did not know that "one in four" means twenty-five percent.[42] The report concluded that "[a] substantial minority of people in this population...could not process simple statistical information....If the consenting process is about informing patients so they can make balanced and reasoned decisions, and the logic behind those decisions is statistical, many cannot give informed consent."[43]

While digesting statistical information may seem daunting to some, developing an understanding of health information can be no less complex. In reviewing the seven elements of informed consent for treatment, it is striking how intrinsic statistics are to the information. The words "risks," "likely results," and "probability" require some sort of statistical interpretation. The patient's lack of statistical understanding, as shown by the British study, puts caregivers in a precarious position. Caregivers can find themselves on a slippery slope—having to retreat backwards in the sophistication of the information presented while looking for a common ground of information that the patient can understand.

Requiring caregivers to prove that patients understand the information presented to them creates yet another difficulty. For example, if, after walking the patient through the seven pieces of information listed above, the caregiver asks his patient if he understands and the patient replies "yes," then what more can society require of the caregiver to determine the accuracy of the patient's answer? Should the

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40. *Id.*; *see also* GEORGE J. ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 30 (1977) (listing five elements that the physician must discuss in lay terms).

41. *Cf.* Carnahan, *supra* note 29, at 575 (noting that patients "commonly do not understand" the risks of medical treatment).

42. Simon J. Ellis et al., Letter to the Editors, *Informed Consent Is Flawed*, 357 LANCET 149, 150 (2001) (citing *National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group, Tissue Plasminogen Activator for Acute Ischaemic Stroke*, 333 NEW ENG. J. MED. 1581–87 (1995)). "44% did not know that a reduction of 25% was a reduction of a quarter; and 43% did not know that a reduction of 25% was equivalent to a reduction of 25 in 100." *Id.* "Informed consent is the bulwark of ethical conduct....[B]ut it is flawed." *Id.*

43. *Id.*

physician give some sort of quiz to the patient in order to ensure his understanding? Detractors of this approach quickly point to the deleterious effect these steps have on the amount of time the caregiver spends actually treating the patient.

By focusing on the questions that they present to patients, physicians can mitigate patients' lack of understanding and provide understandable information that directly benefits the patient.[44] Recognizing that "informed consent...[is] a process involving a series of questions and answers," physicians should be cautioned against "data dumping" on the patient.[45] Rather, patients should be asked how much information they wish to be exposed to, whether they prefer family members or friends to be present during the information exchange, and the type of decision matrix that they prefer to use.[46] In order to satisfy the required elements of informed consent in the treatment context, all of these inquiries should precede the sharing of information between the physician and the patient.[47] This process preserves the principle of autonomy while ensuring that patients give truly informed consent.

C. The Importance of Informed Consent for Research

As with treatment, obtaining informed consent is crucial to ethical research.[48] The Code of Federal Regulations clearly states that "no investigator may involve a human being as a subject in research...unless the investigator has obtained the...informed consent of the subject or the subject's legally authorized representative."[49] These regulations list eight essential elements of information that must be provided to the potential research participant for proper informed consent:

> (1) a statement that the study involves research, as well as a description of the research and its purposes; (2) a description of reasonably foreseeable risks; (3) a description of reasonably expected benefits; (4) disclosure of appropriate alternatives; (5) a statement about maintenance of confidentiality; (6) for research involving more than minimal risk, an explanation of possible consequences if injury occurs; (7) information about how the subject can have questions answered; and (8) a statement that participation is voluntary....[50]

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44. Joal Hill, *Veracity in Medicine*, 362 LANCET 1944, 1944 (2003).

45. *Id.*

46. *Id.*

47. *See id.* (discussing cultural sensitivities to informed consent). Hill's article notes that "interpretation and application [of informed consent] in clinical care are profoundly affected by cultural influences." *Id.* For example, "[i]n Japan, even proponents of shared greater decision-making note that imposing radical notions of autonomy on patients, in which they are forced to receive information whether they want it or not, abrogates the principle of respect for persons and thus autonomy." *Id.*

48. For a detailed discussion of informed consent in medical research, see *infra* Part III.

49. 45 C.F.R. § 46.116 (2005). Further,

> [a]n investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Id.

50. Lisa S. Parker, *Ethical Issues in Bipolar Disorders Pedigree Research: Privacy Concerns, Informed Consent, and Grounds for Waiver*, 4 BIPOLAR DISORDERS 1, 2–3 (2002) (citing 45 C.F.R. § 46.116(a)(1)–(8)).

These elements are different from those required in the treatment context.

The elements of informed consent for research provide additional protection to the research subject. In contrast to the treatment context, the research participant is not provided with information on the effect of non-participation in the study, the probability of success of the study, or the recuperation period involved with participating in the study. Instead, the subject is advised on the confidentiality aspects of participation and the consequences to her should injury occur.[51] Here the distinction between informed consent in the treatment and research contexts is highlighted. The treatment context is focused on the patient's health, while in the research context the patient's well-being becomes secondary to the improvement of society by the creation of generalized knowledge. A separate crucial distinction arises between therapeutic and nontherapeutic research. While therapeutic research focuses on an individual's condition, nontherapeutic research focuses on benefiting the public as a whole.[52] The benefit of therapeutic research on the individual distinguishes it from the unknowns of nontherapeutic research—primarily whether the research subject suffers from the condition that the study is designed to address.[53]

As with treatment, the informed consent process for research has been characterized as an "elaborate ritual" that does not result in true informed consent because of a lack of understanding regarding the risks and benefits of participation.[54] This is true despite the fact that the physician may have adhered assiduously to the informed consent process. Instead, the informed consent process serves only to insulate the researcher from subsequent malpractice claims and fails to provide the subject with the prospective benefit intended by the doctrine.[55] Detractors of the doctrine point to its lack of practical effect and its irrelevance in the research context.[56] If patients do not give true informed consent, and only malpractice claims are impacted, then the process fails.[57]

When appropriate, the participant should also be provided information on:

> (1) unforeseeable risks; (2) circumstances under which the subject's participation will be terminated; (3) additional costs that the subject may incur; (4) the consequences of a subject's decision to withdraw; (5) the dissemination of findings developed during the study that relate to a subject's willingness to continue; and (6) the approximate number of total subjects. The consent must be documented in writing and signed by the subject or his legally authorized representative.

Id. at 3 (citing 45 C.F.R. § 46.116(b)(1)–(6)).

51. *Compare supra* note 40 and accompanying text *with supra* notes 49–50 and accompanying text.

52. For a discussion of the differences between these two types of research, see *infra* Part III.B.

53. *See infra* Part III.B.

54. Carnahan, *supra* note 29, at 575.

55. *See id.*

56. *See, e.g.*, Len Doyal, *Informed Consent in Medical Research: Journals Should Not Publish Research to Which Patients Have Not Given Fully Informed Consent—With Three Exceptions*, 314 BRITISH MED. J. 1107 (1997); Angus J. Dawson, *Methodological Reasons for Not Gaining Prior Informed Consent Are Sometimes Justified*, 329 BRITISH MED. J. 87 (2004).

57. Individual researchers are not the only ones subject to the requirements of the doctrine. *See, e.g.*, Khabir Ahmad, *Drug Company Sued over Research Trial in Nigeria*, 358 LANCET 815 (2001). Pfizer, a major pharmaceutical company, was sued by a group of Nigerian families for failing to obtain the consent of children or their parents before giving them a new, untested drug for bacterial meningitis. *Id.* The article states that "inadequate attention had been paid to the moral duties incumbent on those doing research in poor nations." *Id.* Given this situation, "more and more [Pfizer] type cases could be expected to be brought." *Id.*

While the practical reality of informed consent for research is problematic, the perceptions of the research subjects themselves tell a different story. A recent study of 207 cancer patients enrolled in clinical trials at several major healthcare facilities revealed that ninety percent were satisfied with the informed consent process and most considered themselves to be well informed.[58] Subsequent questioning, however, revealed basic misperceptions regarding the treatment given in the trial.[59] "Many did not realise that the [research protocol] was not proven to be the best for their cancer, that the study used non-standard treatments or procedures, that participation might carry incremental risk, or that they might not receive direct medical benefit from participation."[60] These are, of course, some of the essential elements comprising informed consent.[61]

The perceptions of the researchers also tell a different story. Perhaps of most consequence in this particular study was the fact that only twenty-eight of sixty-one providers (forty-six percent) recognized that the main reason for clinical trials is to benefit *future* patients.[62] The question must then be asked: what do the researchers believe is actually the main reason for clinical trials?

Similarly, a review of thirty-five neonatal randomized controlled trials revealed that ninety-six percent of the trials reported one hundred percent informed consent.[63] This "raise[s] the question as to whether such consent is truly informed—if parents were fully informed of their options and freely able to choose not to take part, at least some would surely choose not to."[64] The fact that so few chose not to take part in the controlled trial suggests flaws in the process of obtaining true informed consent.[65]

What should be done if, as suggested by the studies discussed above, informed consent is flawed or there is not actual consent? In the research arena, commentators have put forth three options: disallow the research, abolish the consent requirement for the research, or accept the imperfections of informed consent while striving to obtain the best consent under the circumstances.[66] One other option, not found in the above-mentioned literature, would simply be to continue to create new exceptions to the doctrine as necessary to fit the current situation. While this option, taken to

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58. Steven Joffe et al., *Quality of Informed Consent in Cancer Clinical Trials: A Cross-Sectional Survey*, 358 LANCET 1772, 1774 (2001). The facilities were the Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Massachusetts General Hospital. *Id.* at 1773.

59. *Id.* at 1774.

60. *Id.*

61. *See supra* note 50 and accompanying text.

62. Joffe et al., *supra* note 58, at 1775. The article acknowledges the difficult situation facing the researchers. "Although our results suggest the need for improvements in informed consent to research, they also point to its complexity in the setting of cancer clinical trials." *Id.* at 1776.

63. Harry Campbell, Letter to the Editors, *Informed Consent in Neonatal Randomised Trials*, 357 LANCET 1445 (2001). Research involving children is covered by a separate set of rules than research involving adults. *See* 45 C.F.R. §§ 46.401–.409 (2005).

64. Campbell, *supra* note 63, at 1445. "One potentially useful approach is to audiotape the obtaining of informed consent and to give the parents [of the participating children] a copy." T.H.H.G. Koh et al., Letter to the Editors, *Informed Consent in Neonatal Randomised Trials*, 357 LANCET 1445 (2001).

65. *See* Campbell, *supra* note 63, at 1445. As a means of emphasizing the seriousness of informed consent, the author recommends that consent rates be expressly stated in each published trial. *Id.*

66. *See* Su A. Mason et al., *Obtaining Informed Consent to Neonatal Randomised Controlled Trials: Interviews with Parents and Clinicians in the Euricon Study*, 356 LANCET 2045, 2050 (2000).

its extreme, will inevitably lead to the exceptions swallowing the rule, it is still a viable option for current practice.

The researchers who engaged in the recent neonatal study preferred the third option of moving forward with the information available.[67] Seventy percent of the cases included some defect in at least one of the elements of informed consent.[68] The researchers listed several strategies for achieving a higher rate of informed consent. Primary among them was to provide information in oral and written formats simultaneously, as well as to inform the patient that the study had been reviewed and approved by research ethics committees.[69] These tactics would help normalize the highly variable results of the published studies—where researchers obtain either no informed consent or imperfect informed consent—while still meeting the technical requirements of the doctrine. Currently, however, informed consent in research is measured by the degree to which the elements described above are met, not the level of the subjects' understanding. If the elements are met, then informed consent theoretically exists. Thus, there will always be some element of doubt as to whether actual informed consent is obtained.

II. INFORMED CONSENT IN THE TREATMENT CONTEXT

The goal of informed consent prior to treatment has always been the same—to focus on the health of the individual patient. One of the primary issues in dealing with informed consent is that the scope of the patient's consent may be limited. This was addressed in the early case of *Schloendorff v. New York.*[70] In *Schloendorff*, the patient agreed to undergo an examination while she was unconscious.[71] The purpose of the examination was to diagnose a lump suspected of being a tumor.[72] While the patient was anesthetized, however, the surgeon removed the tumor.[73] The patient subsequently suffered gangrene and other illnesses as a result of the procedure.[74] The patient contended that she had not authorized the removal of the growth but rather that she had only consented to an examination and diagnosis.[75] She then sued her physician on a battery theory.[76] The New York Court of Appeals held that the physician had battered the patient and should have informed her of the risks and alternatives involved with the treatment prior to taking any action other than what was authorized.[77]

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67. *Id.*

68. *See id.* Specifically, "59 of the 200 parents [of the neonates] [(30%)] had given valid consent or refusal but the remainder had problems in one or more of the component areas (42 for competence, 43 for information, 44 for understanding, and 21 for voluntariness)." *Id.* at 2045.

69. *Id.* at 2050. For a detailed discussion of research ethics committees or institutional review boards, see *infra* Part III.D.

70. 105 N.E. 92 (N.Y. 1914). *See also* Perna v. Perozzi, 457 A.2d 431 (N.J. 1983) (holding that the surgeon who signs the consent form must also be the one to perform the surgery or else there is a battery).

71. *Schloendorff*, 105 N.E. at 93.

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.* at 93–94.

77. *Id.* at 94.

Disclosure of the potential for adverse effects to the patient is a primary element of informed consent.[78] *Natanson v. Kline*[79] was one of the first cases to require disclosure. In *Natanson*, the plaintiff visited a radiation oncologist for follow-up treatment to a mastectomy.[80] The treating physician ordered the administration of radiation to the affected area.[81] The ensuing treatment destroyed skin, muscle, and bone surrounding the plaintiff's chest.[82] The plaintiff sued on the basis that she had not been informed of the potential for the adverse effect.[83] The court held that the treating physician "was obligated to make a reasonable disclosure to the [patient] of the nature and probable consequences of the suggested...treatment, and he was also obligated to make a reasonable disclosure of the dangers within his knowledge which were...possible in...the treatment."[84] Informed consent from the patient was not possible because the physician failed to make a reasonable disclosure. Perhaps realizing that they were only requiring disclosure of what most individuals would deem common sense, the court commented that this type of disclosure should not pose an "insurmountable obstacle[]" to the physician.[85]

The concept of disclosure of adverse effects to the patient was further developed in the famous case of *Canterbury v. Spence*.[86] The court in that case determined which risks must be disclosed to the patient and explicitly stated that a physician owed a duty to her patient.[87] In *Canterbury*, a nineteen-year-old boy underwent surgery for a herniated (or ruptured) disc.[88] Following the surgery, he fell in his hospital room and was subsequently paralyzed from the waist down.[89] He filed suit alleging that his physician had failed to disclose the risk of paralysis to him prior to performing the surgical procedure.[90] The circuit court first found that the physician had a duty to adequately disclose the risks of the procedure to the patient.[91] Second, the court stated that the scope of the required disclosure must include risks that the patient views as material.[92] Specifically, "[a] risk is...material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk...in deciding whether or not to forego the proposed therapy."[93] Under this test, truly remote risks need not be

78. *See* Meisel, *supra* note 5, at 420.
79. 350 P.2d 1093 (Kan. 1960).
80. *Id.* at 1095.
81. *Id.* at 1096.
82. *Id.* at 1097.
83. *Id.* at 1099.
84. *Id.* at 1106.
85. *Id.* at 1107.
86. 464 F.2d 772 (D.C. Cir. 1972).
87. *Id.* at 786–88.
88. *Id.* at 776.
89. *Id.* at 777.
90. *Id.* at 778.
91. *Id.* at 783.
92. *Id.* at 786–88. "[T]he issue on nondisclosure must be approached from the viewpoint of the reasonableness of the physician's divulgence in terms of what he knows or should know to be the patient's informational needs." *Id.* at 787.
93. *Id.* (first alteration in original) (quoting Jon R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 NW. U. L. REV. 628, 640 (1970)).

disclosed.[94] The *Canterbury* court firmly adopted the patient-oriented viewpoint for informed consent because of the requirement that the physician disclose risks that the patient views as material.[95]

The physician must also disclose the risks of the patient's abstention from certain commonplace diagnostic tests.[96] In *Truman v. Thomas*, a patient visited her physician complaining of a recurring urinary tract infection.[97] During the examination and subsequent treatment, the physician advised the patient to submit to a pap smear.[98] The patient did not do so and was later diagnosed with cervical cancer.[99] Expert testimony presented at trial indicated that, had she undergone the pap smear during the five-year period that she was under the care of the physician, the cervical tumor could have been discovered and removed.[100] The patient's children sued on the grounds that her physician failed to inform her of the risks associated with not having the pap smear performed.[101] The physician defended himself on the grounds that he could not force her to undergo the procedure, stating, "I think [the pap smear] is a widely known and generally accepted manner of treatment and I think the patient has a high degree of responsibility. We are not enforcers, we are advisors."[102] The court disagreed, holding that the physician had a duty to disclose the risks associated with not having the pap smear because that information was material to her treatment.[103] Therefore, *Truman* increased the physician's burden of obtaining informed consent by requiring physicians to disclose information that they would normally consider common knowledge.

This line of cases shaped the current state of informed consent in the treatment context. The doctrine focuses on the individual health of the patient. A caregiver has an affirmative duty to disclose the material risks and benefits of a diagnostic procedure or treatment to a patient prior to commencing that care, and to disclose the risks of foregoing treatment. The definition of a material risk is defined from the patient's viewpoint, not the physician's. Failure to disclose the risks breaches the physician's duty and can result in a viable negligence claim against the physician if the patient is injured.

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94. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 367 (5th ed. 2004).

95. The viewpoint was subsequently adopted across the country. *See, e.g.*, Korman v. Mallin, 858 P.2d 1145 (Alaska 1993); Cobbs v. Grant, 502 P.2d 1 (Cal. 1972); Ketchup v. Howard, 543 S.E. 2d 371 (Ga. Ct. App. 2000); Carr v. Strode, 904 P.2d 489 (Haw. 1995); Sard v. Hardy, 379 A.2d 1014 (Md. 1977); Largey v. Rothman, 540 A.2d 504 (N.J. 1988).

96. *See* Truman v. Thomas, 611 P.2d 902, 902 (Cal. 1980).

97. *Id.* at 904.

98. *Id.* The physician testified that he advised the patient to submit to a pap smear, but did not explain the risks of failing to do so. *Id.* The physician, however, was unable to produce records of his recommendation or to recount a specific conversation with the patient. *Id.*

99. *Id.*

100. *Id.*

101. *Id.* at 904–05.

102. *Id.* at 904.

103. *Id.* at 907.

III. INFORMED CONSENT IN THE RESEARCH CONTEXT

A. *The History of the Doctrine*

Informed consent in the research context focuses on the overall benefit of the research study to society, not on the individual health of the research subject.[104] Because of this focus on the improvement of societal health, research participants need additional protections against the potential for injury caused by the study. These protections evolved during the twentieth century as a result of abuse to individual research participants.

1. The Nuremberg Code

Following World War II, Nazi physicians stood trial at Nuremberg for crimes against humanity.[105] During the War, these physicians conducted unauthorized experiments on prisoners of war and civilians of non-German heritage.[106] As a result of the egregious nature of these experiments, the Military Tribunals published the Nuremberg Code in 1946.[107] The Code was the "first major curb on research in any nation"[108] and signaled the beginning of the era of informed consent for research by summarizing the legal requirements for human experimentation.[109]

The Nuremberg Code required that the consent of an experimental subject have four characteristics—it must be voluntary, competent, informed, and understood.[110] The Code's first principle was that "[t]he voluntary consent of the human subject is absolutely essential."[111] By obtaining voluntary informed consent, the individual's autonomy is respected, enabling the research to continue.[112] These elements are similar to the elements required for informed consent in the treatment context.[113] The Code did not permit surrogate consent, which is consent given by an authorized representative or guardian of the subject when the subject is incapacitated.[114] Instead, consent had to be sought solely from the subject.[115]

In addition to describing the required character of the subject's consent, the Code detailed nine principles to be satisfied prior to enrolling the subject in a study.[116] All

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104. *See supra* note 25 and accompanying text.

105. *See* 2 THE NUREMBERG CODE, TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181–82 (1949), *reprinted in* ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 425–26 (2d ed. 1988), *available at* http://www.copernicusgroup.com/irbForms/NurembergCode.pdf (last visited Aug. 20, 2006) [hereinafter TRIALS OF WAR CRIMINALS]. For a succinct summary of the proceedings themselves, see Benjamin B. Ferencz, *Nurnberg Trial Procedure and the Rights of the Accused*, 39 J. CRIM. L. & CRIMINOLOGY 144 (1948) (title spelled as in the original).

106. *See* TRIALS OF WAR CRIMINALS, *supra* note 105, at 425.

107. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 835 (Md. 2001). The Military Tribunals were formed to hear the cases of accused Nazi war criminals.

108. RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 153 (1986).

109. *Grimes*, 782 A.2d at 835.

110. *See* ANNAS ET AL., *supra* note 40, at 7.

111. TRIALS OF WAR CRIMINALS, *supra* note 105, at 181.

112. *See* Carnahan, *supra* note 29, at 570.

113. *See supra* notes 39–40 and accompanying text.

114. TRIALS OF WAR CRIMINALS, *supra* note 105, at 182.

115. *Id.*

116. *See* Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 835–36 (Md. 2001) (quoting George J. Annas, *Mengele's Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17, 19–21

of these principles are centered on protecting the human subject.[117] The Code, however, did not delineate the procedures to be used to obtain informed consent.[118] That was left to the researchers themselves.

The Nuremberg Code resulted from a legal, rather than scientific, approach to the problems of informed consent.[119] Because of this legal focus, duties such as nonmaleficence and respect for a subject's autonomy were imposed upon the researchers.[120] While the Code has never been directly employed as the basis for an award of damages to an experimental subject in the United States,[121] neither has it been disavowed by a court in the United States.[122] Despite this lack of direct application in the United States, the Code served as the basis for other resolutions that refined the requirements of informed consent for subject-based research.

2. The Declaration of Helsinki

Written by the World Medical Association, the Declaration of Helsinki created a code of ethics and standardized guidelines for investigative researchers.[123] Originally published in 1964, it was revised seven times between 1975 and 2004.[124] The Declaration became known as the first attempt at a sort of self-governance by researchers through the development of an ethical code.[125] The document referenced consent throughout and advised that informed consent be obtained in writing from the research subject before commencing the study.[126] It also stated that research

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(1991)). The nine additional principles are (1) the experiment should be useful and necessary, (2) human experiments should be based on previous experiments with animals, (3) physical and mental suffering should be avoided, (4) death and disability should not be expected outcomes of an experiment, (5) the degree of risk taken should not exceed the humanitarian importance of solving the problem, (6) human subjects should be protected against even remote possibilities of harm, (7) only qualified scientists should conduct medical research, (8) human subjects should be free to end an experiment at any time, and (9) the scientist in charge must be prepared to end an experiment at any stage. *See* TRIALS OF WAR CRIMINALS, *supra* note 105, at 181–82.

117. *Grimes*, 782 A.2d at 835.

118. *See* FADEN & BEAUCHAMP, *supra* note 108, at 155.

119. *Grimes*, 782 A.2d at 835.

120. *See id.*

121. *Id.* (quoting Annas, *supra* note 116, at 19–21).

122. *Id.*

123. *Id.* at 849–50.

124. *See* WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2004), http://www.wma.net/e/policy/pdf/17c.pdf [hereinafter DECLARATION OF HELSINKI].

125. *See Grimes*, 782 A.2d at 850.

126. *See* DECLARATION OF HELSINKI, *supra* note 124. The specific provision reads:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and *witnessed.*

Id. ¶ 22 (emphasis added). The 2000 revision added the requirement of obtaining a witness to the non-written consent. *See* Heidi P. Forster et al., *The 2000 Revision of the Declaration of Helsinki: A Step Forward or More Confusion?*, 358 LANCET 1449, 1451 (2001).

should be discontinued if it is determined that the risks of the research outweigh the potential benefits.[127]

Under the Declaration, the researchers have a duty to monitor the harmfulness of the research, while the research subject does not.[128] This duty cannot be abrogated by consent of the patient.[129] This duty is also consistent with the Nuremberg Code because it prevents researchers from immunizing themselves from their duty of care by obtaining consent.[130] The Declaration, however, differed dramatically from the Nuremberg Code by allowing for surrogate consent to be given when the subject was incapacitated.[131]

The most recent revision to the Declaration of Helsinki significantly expanded its breadth. First, there was an expansion of the definition of "vulnerable populations" —i.e., populations that require additional safeguards because of an inability to provide full informed consent.[132] The definition now encompasses virtually every type of subject—"from patients with an illness, to those who cannot give consent, to healthy volunteers....[T]he category of vulnerability [is now so broad] that it eliminates this category as a special protection; if everyone is vulnerable, no one is entitled to special protection."[133] This expansion has led to the effective nullification of special protection for the vulnerable populations. Second, the Declaration is now "a statement of ethical principles" instead of a series of "recommendations."[134] Finally, the Declaration claims supremacy over all other laws and regulations.[135]

The Declaration states that "every patient"—including those of a control group, if any—"should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study."[136] This requirement has had a sweeping effect on placebo-controlled trials where there are already-accepted effective methods of treatment.[137] Essentially, the Declaration forbids researchers from using placebos where there is an existing, proven medical modality for treatment, even if the patient is informed of the existing treatment, declines it, and consents to the trial.[138] The 2000 Declaration contains "no exception for trials done in the specific population of patients who would subsequently benefit from a successful outcome of the research, even when there is adequate patient consent and careful avoidance of any irreversible harm or other ethically unacceptable consequences."[139]

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127. DECLARATION OF HELSINKI, *supra* note 124, ¶ 17.

128. *See Grimes*, 782 A.2d at 850.

129. *See id.*

130. *See id.*

131. *Compare* DECLARATION OF HELSINKI, *supra* note 124, ¶ 26, *with* TRIALS OF WAR CRIMINALS, *supra* note 105, at 181–82.

132. *See* Forster et al., *supra* note 126, at 1451.

133. *Id.*

134. *Id.* at 1449.

135. *Id.* at 1452. The Declaration states that "no national ethical, legal, or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this declaration." DECLARATION OF HELSINKI, *supra* note 124, ¶ 9.

136. *See* DECLARATION OF HELSINKI, *supra* note 124, ¶ 29.

137. *See* John A. Lewis et al., *Placebo-Controlled Trials and the Declaration of Helsinki*, 359 LANCET 1337 (2002).

138. *See id.*

139. *Id.*

Many researchers believe, contrary to the Declaration, that placebo use is still acceptable when it poses no additional risk to the patient.[140] Essentially, this is the position of the Food and Drug Administration, which values the double-blind placebo controlled trial as the "gold standard" among research protocols.[141] A double-blind study eliminates bias and provides scientific certainty by informing neither the researcher nor the subject of which treatments are inactive and which are active.[142] Others believe that the Declaration should allow for the use of placebos even when treatments are available, so long as there is a predictable positive effect to the placebo.[143]

The Declaration has its detractors.[144] It has been criticized for a lack of clarity and "its assertion of supremacy over other guidance and laws."[145] The Declaration created a problem for researchers—they must determine if their research clears two hurdles: the Declaration itself and the requirements of state and federal law.[146] The assumption that researchers will follow the state or federal law when the law does not coincide with the Declaration creates a mixed result by which the Declaration will either be disregarded entirely in favor of the laws of the jurisdiction or there will be uneven application of the Declaration's provisions.[147] This problem is compounded by the Declaration's failure to detail a procedure for addressing ambiguities in its language and its failure to address how to handle potential violations of its rules.[148]

3. The Beecher Article

Two years after the initial publication of the Declaration of Helsinki, Harvard medical school researcher Henry Beecher published a study documenting twenty-two cases of unethical research conducted on human subjects.[149] Beecher's article became enormously influential in the continued evolution of attitudes toward human experimentation.[150] The research that Beecher reviewed was not only harmful to the subjects themselves but had also been subsequently published in prominent medical journals.[151] Through a case-by-case analysis, he demonstrated that the principles of Nuremburg and Helsinki were not yet woven into either the fabric of the medical

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140. *See id.*

141. *See* Carnahan, *supra* note 29, at 577.

142. *See id.* at 578.

143. Thomas, *supra* note 2, at 340. Espousing the contrary view, albeit in irreverent form, is the statement "'I'm addicted to placebos. I could quit, but it wouldn't matter.'" *Id.* at 313 n.1 (quoting Don Mayhew, *Wright on Target from Off Center*, FRESNO BEE, May 8, 1998, at B5 (quoting Steven Wright)).

144. *See* Forster et al, *supra* note 126, at 1452.

145. *Id.*

146. *See id.*

147. *See id.* The article notes that the Food and Drug Administration has refused to incorporate the current version of the Declaration into its rules regarding studies in foreign countries. *Id.*

148. *See id.*

149. *See* Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966). The article begins, "Human experimentation...has created some difficult problems with the increasing employment of patients as experimental subjects when it must be apparent that they would not have been available if they had been truly aware of the uses that would be made of them." *Id.* at 1354.

150. David J. Rothman, *Ethics and Human Experimentation*, 317 NEW ENG. J. MED. 1195 (1987).

151. *See* Carnahan, *supra* note 29, at 571.

establishment or in the media.[152] Beecher noted the difficulty involved in obtaining informed consent but insisted that "it [was] absolutely essential to *strive* for it."[153] And if informed consent is not obtained, a bad situation is quickly compounded if that unethical research is subsequently published in a journal.[154]

Beecher also noted the disparity in position between physicians and patients.[155] "If suitably approached, patients will accede, on the basis of trust, to about any request their physician may make...but the usual patient will never agree to jeopardize seriously his health or his life for the sake of 'science.'"[156] By openly acknowledging the physician or researcher's power over her patients, Beecher reinforced the practical necessity for informed consent. The physician's duty to disclose the risks of research arose from this influence that physicians have over their patients in determining a care plan.

4. The Belmont Report

In 1974, the National Commission for the Protection of Human Subjects of Biomedical Research and Behavioral Research was established in response to Congress's request for direction on the differences between medical treatment and human subject research.[157] The Commission was tasked with identifying the ethical principles implicated when using human subjects.[158] In this task, the Commission paid particular attention to the requirements for informed consent of vulnerable populations in research settings.[159] The Commission's work was published as the Belmont Report in 1979.[160]

The Belmont Report established three basic ethical principles to apply during research involving humans: respect for persons, beneficence, and justice.[161] Of most relevance to this Article is the principle of respect for persons.[162] This principle is based on the belief that individuals are autonomous—they are "capable of deliberation about personal goals and of acting under the direction of such

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152. *See* Beecher, *supra* note 149, at 1356–59. Beecher described the experiments but did not clearly demonstrate how they violated the principles of Nuremberg and Helsinki.

153. *Id.* at 1360. "The statement that consent has been obtained has little meaning unless the subject or his guardian is capable of understanding what is to be undertaken and unless all hazards are made clear." *Id.*

154. *See id.*; *see also* Franklin G. Miller & Donald L. Rosenstein, *Reporting of Ethical Issues in Publications of Medical Research*, 360 LANCET 1326, 1326 (2002) (recommending that "editors of medical journals require authors to discuss ethical issues in reports of clinical research" and noting that "in 1975 the revised Declaration of Helsinki favoured prohibition of publication of unethical research").

155. *See* Beecher, *supra* note 149, at 1355.

156. *See id.*

157. *See* Carnahan, *supra* note 29, at 571; Noah, *supra* note 13, at 387.

158. Establishment of Commission to Protect Research Subjects, Pub. L. No. 93-348, 88 Stat. 349 (1974).

159. *Id.*

160. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 44 Fed. Reg. 23,192 (Apr. 18, 1979), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm.

161. *Id.*

162. The other two principles are of no less importance. The principle of beneficence manifests itself by requiring that an appropriate risk/benefit assessment be performed before research starts. *See id.* The principle of justice requires appropriate subject selection—the population of individuals least likely to benefit from the research should not be over-represented in the study population. *See id.*

deliberation."[163] Individuals with diminished autonomy qualify as vulnerable subjects and are entitled to special protections.[164]

The Report described informed consent as having three components: disclosure of specific items of information, comprehension by the subject of the information provided, and voluntary agreement to participate in the research on the part of the subject.[165] If all three components are satisfied, then informed consent exists and the research may proceed.[166] Similar to the Nuremberg Code and the Declaration of Helsinki, however, the Belmont Report does not state exactly how these three components should be satisfied.[167] Nevertheless, the Report continues to be a guiding factor in applying the law of informed consent.

5. The Code of Federal Regulations

Federal regulations regarding informed consent are a synthesis of two separate sets of guidelines—one issued by the Department of Health and Human Services (HHS) and the other by the Food and Drug Administration (FDA).[168] Prior to the synthesis, the parallel application of the guidelines led to confusion and frustration amongst the research community.[169] HHS regulations applied to any research that was sponsored, regulated, or conducted by a federal department or agency.[170] The FDA regulations applied to any research "intended to support the application for FDA approval of a drug or device."[171]

Because of the difficulty in simultaneously complying with both sets of guidelines, researchers sought to fulfill their ethical responsibilities through "deferred consent" as an alternative consent mechanism.[172] This doctrine allowed research to commence even if the subject was unable to consent. Under deferred consent, an opportunity to consent must be given to the patient or her representative at a later date.[173] One problem with deferred consent was that it placed subjects at the risk of immediate harm without having the opportunity to consent. The practice of deferred consent was halted in 1993 when the Office for Protection from Research Risks, an arm of HHS, stated that deferred consent was not a satisfactory alternative to informed consent and would not satisfy HHS regulations.[174]

Recognizing the difficult position that the competing regulations created for researchers, the HHS and FDA rules were synthesized and published in the Code of Federal Regulations in 1996.[175] Popularly known as the "Common Rule," the new

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163. *Id.*
164. *Id.*
165. *Id.*
166. *See id.*
167. *See id.*
168. Brian T. Bateman et al., *Conducting Stroke Research with an Exception from the Requirement for Informed Consent*, 34 STROKE 1317, 1318 (2003).
169. *Id.*
170. *Id.*
171. *Id.*
172. *Id.*
173. *Id.*
174. *Id.*
175. *Id.* at 1319.

regulations addressed informed consent in detail.[176] They provided for all of the general principles espoused in the Belmont Report.[177] Under the Common Rule, consent must be obtained from the subject or a representative after the subject has had time to ponder the decision.[178] The subject must understand the language used in obtaining consent, and the language must not include provisions that waive the subject's rights or the researcher's liability.[179] The Common Rule also includes exceptions to the general requirement of informed consent.[180]

B. The Distinction Between Therapeutic and Nontherapeutic Research

The distinction between therapeutic and nontherapeutic research lies in the intended benefit to the subject. While the distinction between therapeutic and nontherapeutic research is straightforward, it is particularly crucial when vulnerable populations are involved.[181] For example, guardians of incompetent persons cannot consent to nontherapeutic research, but guardians can consent to an individual's participation in certain therapeutic research.[182]

The purpose of therapeutic research is to "directly help or aid a patient who is suffering from a health condition the objectives of the research are designed to address."[183] This type of research involves treatments that may improve the subject's condition, thus benefiting the individual subject, but have not yet been proven to work. Examples of therapeutic research include "clinical drug trials and the use of experimental medical devices."[184]

Conversely, the additional protections granted to an individual by virtue of status as a research subject are magnified in nontherapeutic research studies. "Nontherapeutic research generally utilizes subjects who are not known to have the

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176. *See* 21 C.F.R. § 50.20 (2006); Robert Steinbrook, *Improving Protection for Research Subjects*, 346 NEW ENG. J. MED. 1425, 1425 (2002).

177. *See* 21 C.F.R. § 50.20.

> [N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Id.

178. *Id.*

179. *Id.*

180. *See infra* Part IV (discussing the exceptions to informed consent that appear in the Code at 21 C.F.R. §§ 50.23–.24 (2006)).

181. *Cf.* Margaret A. Sommerville, *Therapeutic and Non-Therapeutic Medical Procedures—What Are the Distinctions?*, 2 HEALTH L. CAN. 85, 86 (1981) (describing therapeutic and nontherapeutic research and discussing the implications for incompetent persons).

182. *Id.*

183. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 811 n.2 (Md. 2001).

184. Beth Newbury Whitstone, *Medical Decision Making: Informed Consent in Pediatric and Pediatric Research* (2004), http://tchin.org/resource_room/c_art_18.htm; *see also* Kevin O'Rourke, *Informed Consent: Therapeutic and Nontherapeutic Trials* (1994), http://www.op.org/domcentral/study/kor/94051509.htm.

condition the objectives of the research are designed to address, and/or is not designed to directly benefit the subjects utilized in the research, but, rather, is designed to achieve beneficial results for the public...."[185] The research does not normally benefit the research subject directly but is performed to provide others with information for future treatments.[186] Therefore, because of the focus on societal interests, it is essential that an individual subject be informed of the study's lack of individual, therapeutic benefit during the informed consent process.[187]

Nontherapeutic research poses a difficult problem for experimentation and informed consent.[188] The past experiences of Auschwitz[189] and Tuskegee,[190] to name but two, have perhaps labeled nontherapeutic research as an inhumane, unnecessary evil.[191] The most notorious recent example of nontherapeutic research spiraling out of control occurred in *Grimes v. Kennedy Krieger Institue, Inc.*, where otherwise healthy children were exposed to varying levels of lead dust simply to determine if partial lead abatement methods had been successful.[192] The children, being legally incompetent and thus vulnerable, were enrolled in the study by their parents.[193] The parents signed informed consent forms but had not been told of the risks resulting from exposure to the dust.[194] In an opinion that was heavily critical of the institutional review board (IRB) and the researchers, the court held that parents can never consent to nontherapeutic research on their children.[195] While this holding has

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185. *Grimes*, 782 A.2d at 811 n.2.

186. Whitstone, *supra* note 184.

187. *See* O'Rourke, *supra* note 184.

188. *See* LSU L. Ctr., *Maryland Court Imposes Judicial Review on Non-Therapeutic Research on Children*, http://biotech.law. lsu.edu/cases/research/grimes_v_KKI_brief.htm (last visited Apr. 1, 2006).

189. Auschwitz was but one of many Nazi concentration camps operated during World War II. U.S. Holocaust Mem'l Museum, *Nazi Camps*, *in* HOLOCAUST ENCYCLOPEDIA, http://www.ushmm.org/wlc/article.php?lang=en&ModuleId=10005144 (last visited Oct. 13, 2006).

190. The Tuskegee Syphilis Study involved hundreds of poor African-American men infected with the disease. Despite the emergence of penicillin as an effective antidote to the condition, the drug was withheld from the research subjects in order to study the effects of the disease in its advanced state on humans. *See* BARRY R. FURROW ET AL., BIOETHICS: HEALTH CARE LAW AND ETHICS 420 (4th ed. 2001).

191. *See id.*

192. *See* Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 812 (Md. 2001). The standing of nontherapeutic research in the community is not helped by differences of opinion over its definition. For example,

> cancer drug trials are non-therapeutic in that there is no evidence that the drugs are effective against the cancer and many prove not to be. This is clearly non-therapeutic research, but it is also clearly not what [*Grimes*] is concerned with, and it would not be surprising to see an opinion defending the right of the parents of terminally ill children to try anything that might have any benefit, as long as they were not lied to. At the same time, [the *Grimes*] court would probably not permit children who were terminally ill with cancer to be subjects in a phase I HIV trial which included the chance of getting HIV.

LSU L. Ctr., *supra* note 188.

193. *See Grimes*, 782 A.2d at 843–44 (describing consent forms signed by the parents). It is also important to avoid the phenomenon of "therapeutic misconception," which seems to view all nontherapeutic research subjects as being particularly vulnerable. As one author noted, "Special care is needed in ensuring that there is apparent understanding of...information because patients tend to identify physicians with therapy and find it hard to believe that a physician would carry out a non-therapeutic procedure on them, even when they are expressly informed of the fact." Sommerville, *supra* note 181, at 87.

194. *See Grimes*, 782 A.2d at 813.

195. *Id.* at 855. The Maryland appellate court ultimately stated that

> [w]hen it comes to children involved in nontherapeutic research, with the potential for health risks to the subject children...we will not defer to science to be the sole determinant of the ethicality or legality of such experiments....[I]n nontherapeutic research using children, we hold

not been extended to all vulnerable populations, after *Grimes* it is difficult to imagine a set of circumstances in which a vulnerable or incompetent individual's guardian could consent to nontherapeutic research involving the individual.

C. The Effect of the Doctrine on Research Methodology

Informed consent in the research context raises several problems. Chief among them are ensuring subject comprehension, mitigating selection bias, and ensuring that any economic interests of the researchers play no role in the conduct of the research study. Informed consent serves six functions in the research context: (1) to promote individual autonomy; (2) to protect the patient-subject's status as a human being; (3) to avoid fraud and duress; (4) to encourage self-scrutiny by the physician-investigator; (5) to encourage rational decision making; and (6) to involve the public.[196] But the list can generally be distilled down to two primary principles—promoting individual autonomy and encouraging rational decision making.[197] These two principles are similar to those in the treatment context.[198] By ensuring that the patient or representative is in control of the overall decisions regarding treatment, and that the patient's decisions are educated and systematic, the researchers meet the requirements for informed consent. The researchers themselves directly benefit from obtaining this informed consent because it generally minimizes the risk of a lawsuit being brought by the subject.[199] If the patient perceives that she is involved in the process, and actually in control of the process, the risk of a lawsuit decreases. As a group, society also benefits from ensuring patient autonomy and rational decision making because these factors facilitate productive and accurate research.[200]

Informed consent in research suffers from the same problem of patient or subject comprehension that exists during treatment. The difficulty of assuring actual patient or subject comprehension is illustrated by a recent study conducted in Haiti.[201] The study involved testing volunteers' understanding of a consent form before they signed the form.[202] Study participants were given the opportunity to seek clarification of any elements on the form during the informed consent process.[203] The researchers concluded that a single meeting to discuss a subject's involvement in a trial might be insufficient to ensure that the subject comprehends the study and that a series of meetings greatly increased a subject's understanding of the consent

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that the consent of a parent alone cannot make appropriate that which is innately inappropriate.

Id. The parent-child relationship has been expanded to include all vulnerable populations. "[I]t is not possible for a guardian...to consent to a non-therapeutic research intervention on an incompetent person in his or her care." Sommerville, *supra* note 181, at 86.

196. *E.g.*, ANNAS ET AL., *supra* note 40, at 33.

197. *See, e.g., id.* at 34; JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 76 (1987).

198. *See supra* notes 33–37 and accompanying text.

199. Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786, 1787 (1995). "The possibility of unhappiness and even litigation later on may be greatly reduced by early disclosure, discussion, and the opportunity to refuse to participate." *Id.*

200. *See id.* Further, "society benefits from the communal commitment embodied in an individual's knowing decision to participate in research." *Id.*

201. Daniel W. Fitzgerald, *Comprehension During Informed Consent in a Less-Developed Country*, 360 LANCET 1301, 1301 (2002).

202. *Id.*

203. *Id.*

form.[204] Attempting to obtain informed consent in a single, discrete encounter led to overload and might be a wasted effort for all parties involved.[205] Further, the participants were illiterate, and the need to communicate without writing limited the amount of information that could be discussed at each meeting.[206]

The results of the study reinforce the idea that informed consent is a process, not a discrete event. For the process to function correctly, the information flow from the researchers to the participants must be monitored by the researchers to ensure that the subjects do not become saturated with information and that true informed consent occurs. In addition to the problem of subject comprehension, other hurdles to overcome include selection bias and the economic interests of the researchers themselves.

1. Selection Bias

From a purely scientific point of view, ensuring that participation is limited only to subjects that have proven that they fully understand the information presented can lead to selection bias.[207] In a recent observational study, researchers found that the informed consent process was inadequate for the needs of most subjects despite meeting all of the elements of informed consent.[208] The researchers found that only twenty-two percent of the participants were sufficiently educated to understand the information presented, and only eighteen percent of the participants actually read the consent forms before making a decision as to participation in the trial.[209] Unfortunately, those subjects who were incapable of giving informed consent may actually be the ones who would most benefit from participation in the study.[210] As a result, researchers may be left in a frustrating position in which a group of individuals could truly benefit from the research but is prevented from participating because of the inability to obtain informed consent from the individual members of the group.

The researchers ultimately concluded that the informed consent process could be a substantial barrier to the inclusion of some necessary populations in a study.[211] Clearly this is undesirable because it raises the possibility that researchers are more concerned with completing their studies than they are in complying with the informed consent process. The fact that one does not hear of a research study being cancelled because informed consent could not be obtained implies that unethical research currently continues.

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204. *Id.* at 1301–02. The informed consent process occurred during three separate thirty to forty minute sessions over a span of seven to ten days. *Id.* at 1301.

205. *Id.* at 1302.

206. *Id.*

207. *See* Nina Hannover Bjarnason & Jens Peter Kampmann, Letter to the Editors, *Selection Bias Introduced by the Informed Consent Process*, 361 LANCET 1990, 1990 (2003). "The randomised controlled trial is the cornerstone for assessment of new therapies, but its value as a true sample of the total population is highly dependent on the recruitment process." *Id.*

208. *Id.*

209. *Id.*

210. *Id.* There is a similar concern with emergency patients. *See infra* Part IV.B.2.

211. Bjarnason & Kampmann, *supra* note 207, at 1990.

2. Economic Interests of the Researchers

The duty to obtain informed consent does not necessarily require researchers to disclose their economic interests.[212] A federal district court in Florida ruled in 2003 that a physician researcher did not breach his duty to obtain informed consent when conducting medical research on blood and tissue samples of volunteer subjects.[213] The subjects suffered from Canavan's disease, a fatal genetic disorder.[214] At the time the study began, there was no mechanism to identify carriers of the disease-causing gene.[215] The plaintiffs approached a single researcher to perform the genetic research.[216] Once the gene was isolated, the researcher obtained a patent for work based on the subjects' samples.[217] The subjects brought a suit demanding that the research results remain in the public domain to assist other researchers with finding a cure for the disease.[218] They alleged that the physician had not informed them of his intention to seek a patent on the research and by doing so had breached his duty of informed consent.[219]

In finding for the defendant physician, the court ruled that the duty to disclose extended to the actual research alone, not to the researcher's economic interests (such as patents).[220] The court recognized, however, that this area of law was "unsettled and fact-specific...[and] that in certain circumstances a medical researcher does have a duty [to obtain] informed consent" when economic interests are at issue.[221] The court gave no explanation for this statement, leaving one to wonder exactly what those certain circumstances could be. The court concluded its analysis of the informed consent claim by acknowledging the American Medical Association's Code of Ethics guidelines for physicians and researchers.[222] The court observed that that the guidelines require potential commercial applications to be disclosed to the subject before the researcher engages in profit-seeking activity.[223] Nevertheless, the court accorded the rule little deference, refusing to factor the rule into its analysis.[224]

When one considers the possibility that a researcher's motives might be influenced to some extent by the potential for profit, this seems an odd result.[225]

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212. *See* Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1070–71 (S.D. Fla. 2003).

213. *Id.*

214. *Id.* at 1066.

215. *Id.*

216. *Id.*

217. *Id.* at 1067.

218. *Id.* at 1068.

219. *Id.*

220. *Id.* at 1069–71.

221. *Id.*

222. *Id.* at 1070 n.2.

223. *Id.*

224. *Id.* The court stated that "these regulations were only promulgated in 1994 and there is no evidence that they bind the parties in this case." *Id.* This is a strange result, considering the court's opinion was written in 2003—nine years after the regulations were published.

225. For a discussion of financial conflicts of interest among researchers and the potential deleterious effects on research subjects, see Bernard Lo et al., *Conflict-of-Interest Policies for Investigators in Clinical Trials*, 343 NEW ENG. J. MED. 1616 (2000). The authors find a substantial disparity among conflict of interest policies at the ten medical schools receiving the most funding from the National Institutes of Health. *Id.* at 1616. Among the

When research is involved, subjects of studies require more protection than patients receiving treatment because there is no direct benefit to the research subject, as opposed to the treatment of a patient. The court should have followed the AMA guidelines that require a physician to discuss economic issues with the research subject, because this would have provided the participant with complete information on the range of the study.

D. The Oversight of Research and Informed Consent by Institutional Review Boards

Recognizing that additional protections are needed in the research context, federal regulations require institutional review boards (IRBs) to ensure that research studies are conducted ethically and with the full informed consent of the participants.[226] IRBs provide the initial approval of a research study and then conduct a continuing review of the study to ensure ongoing compliance with institutional policies and procedures.[227] By federal statute, IRBs "review and have authority to approve, require modifications in...or disapprove all research activities [of their parent organization]."[228] IRBs are responsible for mitigating unnecessary risks for subjects enrolled in research protocols[229] and for guarding against the exploitation of those subjects.[230] The specific role of the IRBs is to assure the protection of research subjects and "to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice."[231] When certain conditions are met, IRBs may also waive the informed consent requirement for studies under their purview.[232]

IRBs do not always effectively protect research subjects. One of the reasons for this is the composition of the membership. An IRB's membership must be composed of a minimum of five members, at least one of whom must be a layperson.[233] Because the majority of the members are physicians and other healthcare professionals, the probability of receiving approval from an IRB is much higher than if there were a greater number of lay members.[234] Some argue that an

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recommendations to address the problem is the implementation of a prohibition on stock or stock option ownership in the companies involved with the research. Nor should researchers hold positions of authority in a company potentially affected by their research results. *Id.* at 1619.

226. *See* Robert D. Truog et al., *Is Informed Consent Always Necessary for Randomized, Controlled Trials?*, 340 NEW ENG. J. MED. 804, 806 (1999); Halikas v. Univ. of Minn., 856 F. Supp. 1331, 1334 (D. Minn. 1994) ("The IRB is the mechanism by which a medical research institution maintains [its] integrity and humanity.").

227. *See* 45 C.F.R. § 46.109(e) (2005).

228. *Id.* § 46.109(a).

229. *See* Robert Steinbrook, *Trial Design and Patient Safety—The Debate Continues*, 349 NEW ENG. J. MED. 629, 630 (2003).

230. *See* Truog et al., *supra* note 226, at 806.

231. 45 C.F.R. § 46.107(a) (2005).

232. *See id.* § 46.116(d) (2005). For a detailed discussion of waiver in the research context, see *infra* Part IV.D.2.

233. *See* 45 C.F.R § 46.107(a). "Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas." *Id.* § 46.107(c). The National Bioethics Advisory Commission recommended that members whose primary concerns are in nonscientific areas should comprise at least twenty-five percent of IRB membership. *See* Steinbrook, *supra* note 176, at 1428.

234. H. Peter Steeves, *"Start a Line and Get Me a Consent Waiver, STAT!": Autonomy, Community Consultation, and Informed Consent in Emergency Research*, Special Issue, QUEEN 44, http://www.ars-

inherent conflict of interest exists because IRB members are potentially reluctant to pass judgment on their own colleagues' research due to the fact that they could find themselves applying to an IRB in the future for permission to conduct research.[235] This result persists despite the fact that the federal regulations prohibit members with conflicts of interest from participating within the IRB.[236]

IRBs can also experience difficulty in remaining true to their mission. In *Grimes v. Kennedy Krieger Institute, Inc.*, a Maryland appellate court stated that IRBs can place a premium on the success of experiments, often to the detriment of the ethicality of experiments.[237] In that case, the IRB encouraged researchers to misrepresent the purpose of a study in order to guarantee a lower level of scrutiny.[238] By encouraging misrepresentation, the IRB overlooked "its primary role...to assure the safety of human research subjects—not help researchers avoid safety or health-related requirements. The IRB, in this case, misconceived, at least partially, its own role."[239] Because the study involved children, a vulnerable population, it drew close scrutiny from the court.[240] The court found that the children were healthy at the onset of the study and that there was no therapeutic benefit to them from participation in the research.[241] In ruling against the researchers, the court held that (a) there was no informed consent because this information was withheld and (b) "a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject."[242] The court in *Grimes* was the first to recognize this rule.[243] The special relationship between subject and researcher now clearly extended to the IRB.[244]

A recent analysis of effectiveness providing both criticisms of and recommendations for the role of IRBs was presented to the Government Reform and Oversight Committee of the U.S. House of Representatives in 1998.[245] The resulting report concluded that IRBs conducted only minimal ongoing review of research that

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rhetorica.net/Queen/VolumeSpecialIssue/Articles/Steeves.pdf (last visited Oct. 13, 2006). A rather vivid analogy is painted by describing an IRB packed with physicians as "'putting Dracula in charge of the blood bank.'" *Id.* (quoting Paul McNeill, *International Trends in Research Regulation: Science as Negotiation*, *in* RESEARCH ON HUMAN SUBJECTS: ETHICS, LAW AND SOCIAL POLICY 243, 245 (David N. Weisstub ed., 1998)).

235. *See* Carnahan, *supra* note 29, at 586–87.

236. *See* 45 C.F.R. § 46.107(e) ("No IRB may have a member participate in [an] initial or continuing review of any project in which the member has a conflicting interest...."); *see also* Steinbrook, *supra* note 176, at 1426 ("If the [IRBs] are effective, they may block or delay the approval of research that is important to the financial health and reputation of the institutions that created them.").

237. *See Grimes*, 782 A.2d 807, 817 (Md. 2001). IRBs "are not designed...to be sufficiently objective in the sense that they are as sufficiently concerned with the ethicality of the experiments they review as they are with the success of the experiments." *Id.*

238. *Id.*; *see supra* Part III.B.

239. *Grimes*, 782 A.2d at 814.

240. *Id.* at 817.

241. *Id.* at 815; *see supra* Part III.B.

242. *Grimes*, 782 A.2d at 858. This has obvious echoes of the Nuremberg Code, which does not allow for surrogate consent of any kind. *See* TRIALS OF WAR CRIMINALS, *supra* note 105, at 181–82; *see also supra* Part III.A.1 (discussing the Nuremberg Code).

243. *See Grimes*, 782 A.2d at 846.

244. *Id.* at 817.

245. *Institutional Review Boards: A System in Jeopardy: Hearing Before the Subcomm. on Human Res. of the H. Comm. on Gov't Reform & Oversight*, 105th Cong. 14 (1998) (statement of George F. Grob, Deputy Inspector General for Evaluation and Inspections, Department of Health & Human Services).

they had approved,[246] that too much was reviewed at too great a speed,[247] that insufficient resources were allocated for self-analysis of effectiveness,[248] and that little training was provided to its members or to the researchers themselves.[249]

The study made several recommendations for improvement to the IRB environment.[250] These recommendations included granting more flexibility to the IRBs in order to increase their accountability, re-engineering the federal oversight process to include criteria for the recruitment and selection process of subjects, and improving the education that IRB members and researchers receive.[251]

Responding to these recommendations, the Department of Health and Human Services established the Office for Human Research Protections (OHRP) in 2000.[252] The OHRP was charged with the regulation of "institutions and other entities that conduct or oversee studies involving human subjects."[253] Under these regulations, IRBs fell under the jurisdiction of the OHRP, which regulates and investigates complaints related to IRBs.[254] The OHRP's authority is derived from the written pledge that research organizations sign in which they agree to comply with federal regulations.[255]

The FDA also took steps to monitor the work of IRBs and to ensure subject protection by establishing the Office for Good Clinical Practice in 2001.[256] The Office is responsible for approximately 50,000 active clinical investigators and 2,500 IRBs.[257] Not to be outdone, in 2002 the National Institute of Health announced a $28.5 million program designed to assist institutions in monitoring their ongoing clinical research.[258]

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246. *Id.* at 17–18. "One IRB member told us that he reviews the continuing review summaries during the board meeting to see if a patient has died. If no patient has died, then he generally will not raise questions." *Id.* at 17.

247. *Id.* at 18–19. "We found average increases of 42 percent in initial reviews during the past 5 years at the sites we visited." *Id.* at 18.

248. *Id.* at 19–22. Admittedly this is because there is little empirical data with which to conduct such an evaluation. *Id.* at 20–21. The dean of one medical school thought that the IRB was doing a good job if they did not contact him. *Id.* at 20. But IRBs have rarely sought feedback from the researchers or the subjects. *Id.*

249. *Id.* at 22–23. "For new IRB members, their orientation to the role is seldom much more than a stack of materials to read and on-the-job learning." *Id.* at 23.

250. *Id.* at 23–27.

251. *Id.*

252. *See* Steinbrook, *supra* note 176, at 1426; U.S. Dep't of Health & Human Servs., Office for Human Research Protections, http://www.hhs.gov/ohrp/ (last visited Sept. 10, 2006).

253. Steinbrook, *supra* note 176, at 1426. The OHRP's Director has stated that its mission is clear-cut. "'It is not as if we need another thoughtful analysis of things....All we need in some respects is an action plan.'" *Id.*

The scope of OHRP's activities is broad. *See* U.S. Dep't of Health & Human Servs., OHRP Fact Sheet, http://www.hhs.gov/ohrp/about/ohrpfactsheet.pdf (last visited Sept. 10, 2006). Amongst the Office's specific duties are serving as the compliance enforcement arm of HHS-approved human subject research, investigating all allegations of noncompliance, offering guidance on statutory interpretation, and providing educational programs on the human subject research process. *Id.*

254. *See* Steinbrook, *supra* note 176, at 1426.

255. *Id.* at 1425–26.

256. *Id.* at 1427.

257. *See id.*

258. *See id.* at 1429. The National Institutes of Health (NIH) is the principal federal agency providing funds for biomedical research. Its mission is to ensure that the funded research complies with HHS regulations. NIH also issues its own guidelines for data and safety monitoring, as well as education of the researchers themselves. *See* Nat'l Insts. of Health, Questions and Answers About NIH, http://www.nih.gov/about/Faqs.htm#NIH (last visited Nov. 29, 2006).

Meanwhile, the number of IRBs continues to grow.[259] Between 1999 and 2002, seven of the eleven schools receiving the largest amount of financial support from the National Institute of Health added IRBs.[260] While this increases the burden on the governmental agencies established to supervise these organizations, it should ease the workload of the individual IRBs themselves.

IV. EXCEPTIONS TO THE DOCTRINE

The requirements of informed consent may be modified or disregarded under certain circumstances.[261] These circumstances create exceptions to the doctrine in both the treatment and research contexts. While the exceptions to informed consent for treatment can be distinguished from each other, they all focus on championing the individual's health.[262] This value focuses on "the health of the individual for the individual's own sake, the maintenance and promotion of the health of loved ones, and the assurance that the medical and related professions are free to practice responsibly in accordance with sound professional dictates."[263] The exceptions for research studies arise as a result of the difficulty in finding an adequate number of subjects for the studies.[264]

There are four generally recognized exceptions to the requirement to obtain informed consent.[265] First, consent is presumed in the diagnostic phase of therapy. Second, a patient may not be competent to make an informed decision, usually in the case of an emergency. Third, disclosure may be harmful to the patient. Fourth, patients may waive their right to informed consent.[266] Also included in the list of exceptions are low-risk surgeries, common procedures, or procedures such as childbirth that do not require a decision.[267]

A. Presumed Consent

1. In the Treatment Context

Although the common law generally does not allow the treatment of an individual without his informed consent, in some cases consent may be presumed.[268] In diagnostic situations such as drawing blood, taking a temperature, or conducting routine physical exams, obtaining the informed consent of the patient is unnecessary

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259. *See* Steinbrook, *supra* note 176, at 1428.

260. *See id.*

261. *See, e.g.*, BERG ET AL., *supra* note 197, at 76.

262. *See* Meisel, *supra* note 5, at 487.

263. *See id.*; Charles Marwick, *Assessment of Exception to Informed Consent*, 278 JAMA 1392, 1393 (1997). Some believe that the recognition of exceptions to the doctrine creates a slippery slope that erodes individual protections. In referring to the exceptions, for example, one IRB member commented, "'We gave people the right to informed consent, now we have turned around and taken it back.'" *Id.*

264. *See* Carnahan, *supra* note 29, at 567.

265. *See, e.g.*, Rich, *supra* note 1, at 329.

266. *See id.* at 329–30.

267. J.D. LEE & BARRY LINDAHL, 3 MODERN TORT LAW: LIABILITY AND LITIGATION § 25:40 (2d ed. 2003).

268. *E.g.*, Carnahan, *supra* note 29, at 574; *see also* The United Kingdom Parliament (House of Commons) Organ Donation (Presumed Consent and Safeguards) Bill (Feb. 3, 2004), *available at* http://www.publications.parliament.uk/pa/ cm200304/cmbills/047/2004047.htm (discussing presumed consent for donating organs upon death).

because the procedures are only diagnostic and are minimally invasive.[269] The presumption of consent stems from the physician-patient relationship, in which it is understood that the physician will do no harm to the patient and will perform the necessary procedures to diagnose the patient's illness. Requiring the patient's informed consent is unnecessary in the diagnostic stage because treatment has not yet begun.

Courts, however, have not always hewn to this distinction between diagnosis and treatment. In *Morgan v. MacPhail*, the Pennsylvania Supreme Court did not distinguish between diagnostic and therapeutic procedures, but rather based its analysis on the distinction between medical and surgical procedures.[270] In doing so, the court held that the requirement to obtain informed consent applied solely to surgical procedures.[271] Thus, the non-surgical administration of medication fell outside the doctrine and did not require consent. In *Morgan*, the plaintiff sued her physician for failing to inform her of potential side effects from nerve block injections.[272] The court held that actions for breach of informed consent were only appropriate for surgical procedures, because they involved the physical contact necessary to sustain a battery action:[273]

> The rationale underlying requiring informed consent for a surgical or operative procedure and not requiring informed consent for a non-surgical procedure is that the performance of a surgical procedure upon a patient without his consent constitutes a technical assault or a battery because the patient is typically unconscious and unable to object....The patient, appellants urge, has the right to make an informed choice as to electing to undergo a medical procedure after having been presented with the alternatives and the risks attendant to each alternative. This argument, however, flies in the face of the traditional battery theory. It is the invasive nature of the surgical or operative procedure...that gives rise to the need to inform the patient of risks prior to surgery.[274]

The dissent in *Morgan* pointed out that "there is no basis to require informed consent before surgery but not before other medical procedures."[275] The dissenting justice stated the obvious: "Many non-surgical procedures involve a touching and may be technical batteries without informed consent just like surgery....[I]nformed consent should be required for medical procedures beyond surgery."[276] He concluded that "there is no basis to distinguish between surgical and non-surgical procedures in the law of informed consent."[277]

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269. *But see* Truman v. Thomas, 611 P.2d 902, 907 (Cal. 1980) (holding that diagnostic tests require the informed consent of the patient). *See also supra* Part II (discussing *Truman*).

270. 704 A.2d 617 (Pa. 1997).

271. *Id.* at 619–20.

272. *Id.* at 618–20.

273. "It has long been the law in Pennsylvania that a physician must obtain informed consent from a patient before performing a surgical or operative procedure. Informed consent, however, has not been required in cases involving non-surgical procedures." *Id.* at 619–20 (citations omitted).

274. *Id.* at 620 (citation omitted).

275. *Id.* at 621 (Nigro, J., dissenting).

276. *Id.* at 622.

277. *Id.* at 621.

The majority's reasoning in *Morgan* is an anomaly. One can only assume that the court was determined not to apply a negligence standard when evaluating informed consent, unlike the rest of the country. The prevailing view remains that informed consent is required for all medical and surgical treatment, unless consent is presumed for diagnostic procedures.[278]

2. In the Research Context

There is no presumed consent in the research context because of the increased protection given to research subjects.[279] The Code of Federal Regulations, however, provides for several research settings where informed consent is not required. These include research on educational or interview methods or techniques;[280] research involving the analysis of publicly available, anonymous specimens;[281] research involving the analysis of public service programs;[282] and research involving the taste and quality of foods.[283] These studies, unlike medical research, do not require the informed consent of the subjects because they do not involve actual subject interaction. Instead, the researchers are simply engaging in the analysis of data. If necessary, however, the regulation provides for protection of the subjects by allowing for federal department or agency heads to impose informed consent requirements on these types of studies, regardless of the regulatory provisions.[284]

3. Genetic Research and the Collection of Data

The crossroads of a physician's duty to warn a patient of a genetically inheritable disease and the right to informed consent is gaining increased attention.[285] The

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278. *See supra* Part I.B.

279. *See* Michelle H. Biros, *Research Without Consent: Current Status, 2003*, 42 ANNALS EMERGENCY MED. 550, 551 (2003).

280. *See* 45 C.F.R. § 46.101(b)(1)–(2) (2005).

> Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Research involving the use of educational tests,...survey procedures, interview procedures or observation of public behavior....

Id.

281. *See id.* § 46.101(b)(4) ("Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.").

282. *See id.* § 46.101(b)(5) ("Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs....").

283. *See id.* § 46.101(b)(6).

> Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Id.

284. *See id.* § 46.101(b) ("Unless otherwise required by department or agency heads....").

285. *See* Pate v. Threlkel, 661 So. 2d 278, 282 (Fla. 1995) ("[I]n any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient.").

dueling interests of a patient's right to consent to the use of individual genetic information contrasted with the potential effect of that information on another's health (or wallet) is an issue that is being debated on the national stage. The U.S. Senate's recent passage of the Genetic Information Nondiscrimination Act is one example of this national interest.[286] The bill bans discrimination by insurers based on an individual's genetic blueprint and is one of the first pieces of national legislation aimed solely at genetics.[287]

Professionals within the field have a strong predilection toward self-determination in genetic testing.[288] That is, receiving advice regarding genetic testing is based on an individual's informed consent: once people learn of the risks and available options, educated decisions based on personal values and beliefs can then be made.[289] Some commentators urge that this decision—whether to learn of one's genetic predisposition—should be protected under the Due Process Clause, akin to other privacy rights.[290]

The American Society of Human Genetics' *Statement on Informed Consent for Genetic Research* outlined a few of the key issues in the field.[291] It encouraged anonymization of genetic samples derived from research or, alternatively, full informed consent.[292] The informed consent was broad in its requirements but allowed for waiver.[293] Satisfaction of the requirements for waiver, however, still leaves several issues unresolved.

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286. *See* Genetic Information Nondiscrimination Act, S. 306, 109th Cong. (2005); Brian DeBose, *Senate Votes to Ban Bias Based on Genetic Makeup*, WASH. TIMES, Feb. 18, 2005, at A6, *available at* http://www.washingtontimes.com/functions/print.php?StoryID=20050217-114810-9747r.

287. *See* Genetic Information Nondiscrimination Act, S. 306 § 2. "Genetic information" is defined in the bill as "information about (i) an individual's genetic tests; (ii) the genetic tests of family members of the individual; or (iii) the occurrence of a disease or disorder in family members of the individual." *Id.* § 201(5).

288. Sonia M. Suter, Note, *Whose Genes Are These Anyway? Familial Conflicts over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1894 (1993).

289. *Id.*

290. *Id.* at 1905. "Legislation or judicial decisions should be made with an eye toward encouraging informed consent, education, and genetic counseling services so that people can determine whether genetic testing is appropriate for them." *Id.* at 1906.

291. American Society of Human Genetics, *Statement on Informed Consent for Genetic Research*, 59 AM. J. HUMAN GENETICS 471, 471 (1996).

292. *Id.*

293. *Id.*

> Subjects providing consent for prospective studies should be told about the types of information that could result from genetic research. Subjects must be given sufficient information to understand the implications and the limitations of research. Individuals should be told the purpose, limitations, possible outcomes, and means of communicating results and maintaining confidentiality....the possibility of adverse psychological sequelae, disruption of family dynamics, and social stigmatization and discrimination.
>
> The consent form should not promise significant breakthroughs in diagnosis, treatment or outcome to entice participation.
>
> ....
>
> It is inappropriate to ask a subject to grant blanket consent for all future unspecified genetic research projects on any disease or in any area if the samples are identifiable in those subsequent studies.
>
> Subjects involved in studies in which the samples are identified or identifiable should indicate if unused portions of the samples may be shared with other researchers.

Id. at 473–74. The Statement points out that, while waiver is permitted when identifiable samples are used, the research subject should be contacted again to confirm consent. Then the four-part waiver test is employed. *See infra* Part IV.D.2.

While one of the prerequisites for waiver is "minimal risk,"[294] defining that term in the context of genetic research is problematic.[295] Customary use of the phrase refers to minimal *physical* risk, but physical risk is largely confined to drawing the blood sample involved with genetic research.[296] Instead, social and psychological risks must be taken into consideration. The traditional informed consent doctrine has not contemplated risk in these terms, and precisely how to account for them is a topic of some debate.

The Secretary's Advisory Committee on Genetic Testing recently struggled with this issue in the regulatory context.[297] In attempting to develop a Proposed Rule for genetic testing, the committee ultimately "concluded that fundamental, irresolvable questions had been raised about the feasibility of categorizing tests for oversight purposes based on a limited set of elements in a simple, linear fashion....[and] decided that further efforts to develop a classification methodology for genetic tests should be curtailed."[298] The Committee essentially decided to relegate the task of developing a classification methodology for genetic testing to the FDA.[299] The FDA has yet to publish a proposal for the regulatory classification of genetic research, including a risk classification system.

Extreme care must be taken to inform the subject of possible future uses of genetic material.[300] As in *Greenberg*, courts have acknowledged that there are certain situations where a researcher must inform his subjects of the economic interests raised by the research.[301] It is but a short step from economic interests to the interests of family members, the public, the media, or other third parties.

Of further concern are international efforts such as the building of a national genetic database by a private company in Iceland.[302] While the intent of the database is to address public health concerns in the country and to allow for the development of commercial products,[303] it employs presumed consent with an opt-out provision—a system supported by seventy-five percent of the country.[304] However, one wonders if the population understands precisely how accessible their genetic data will be. While the data is intended to be anonymized, doubts have been raised

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294. Amy A. Ernst et al., *Minimal-Risk Waiver of Informed Consent and Exception from Informed Consent (Final Rule) Studies at Institutional Review Boards Nationwide*, 12 ACAD. EMERGENCY MED. 1134, 1134 (2005).

295. LORI B. ANDREWS ET AL., GENETICS: ETHICS, LAW AND POLICY 108 (2002).

296. *See id.* at 104 (noting that once a sample is drawn, making the donor anonymous eliminates the need to obtain informed consent for further research).

297. *See* SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, NAT'L INSTS. OF HEALTH, ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT 7 (2000), http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf.

298. SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, NAT'L INSTS. OF HEALTH, DEVELOPMENT OF A CLASSIFICATION METHODOLOGY FOR GENETIC TESTS: CONCLUSIONS AND RECOMMENDATIONS OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETIC TESTING 11 (2001), http://www4.od.nih.gov/oba/sacgt/reports/Addendum_final.pdf.

299. *Id.*

300. *See* Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064 (S.D. Fla. 2003); *see supra* Part III.C.2.

301. *See Greenberg*, 264 F. Supp. 2d at 1070.

302. *See* Ross Anderson, *The DeCODE Proposal for an Icelandic Health Database* (1998), http://www.ftp.cl.cam.ac.uk/ftp/users/rja14/iceland.pdf.

303. *See* Jamaica Potts, *At Least Give the Natives Glass Beads: An Examination of the Bargain Made Between Iceland and deCode Genetics with Implications for Global Bioprospecting*, 7 VA. J.L. & TECH. 8, 24–25 (2002).

304. *Id.* at 24 n.71. The support rate grew to ninety-one percent in polls taken after passage of the bill. *Id.*

about the capability of actually de-identifying individual genetic data.[305] If even some of those doubts are true, then there has been a major break from the traditional informed consent doctrine mandating that identifiable health information must not be accessible without the patient's consent.[306]

B. Incompetence

Individuals who are incompetent as a result of a mental disability, such as schizophrenia, are distinguished from those who are incompetent as a result of an emergency situation, such as a heart attack or stroke. Informed consent requirements for patients with mental disabilities are met through the use of surrogates or legal representatives for the patients.[307] Informed consent requirements for incompetent patients in emergency situations are met through the application of surrogate consent, presumed consent, or an exception to the doctrine that allows for treatment without informed consent.

1. Emergency Treatment

The emergency treatment exception applies "when there is a sudden marked change in the patient's condition so...action is immediately necessary for the preservation of life or the prevention of serious bodily harm to the patient or others...."[308] Specifically, informed consent is not required

> when the patient is unconscious or otherwise incapable of consenting, and harm from a failure to treat is imminent and outweighs any harm threatened by the proposed treatment. When a genuine emergency of that sort arises, it is settled that the impracticality of conferring with the patient dispenses with the need for it. Even in situations of that character the physician should, as current law requires, attempt to secure a relative's consent if possible. But if time is too short to accommodate discussion, obviously the physician should proceed with the treatment.[309]

The emergency treatment "exception" actually encompasses several concepts—implied consent,[310] presumed consent,[311] and surrogate consent.[312] For example, at the scene of an accident paramedics do not seek consent prior to removing the patient from his car, nor do they seek permission to initiate cardiopulmonary

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305. Anderson, *supra* note 302, at 3. ("[I]t is effectively impossible to de-identify longitudinal records, that is, records which link together all (or even many) of the health care encounters in a patient's life."). There is at least some evidence that deCode publicly acknowledged this fact. *Id.* at 4.

306. *See id.* at 4, 11.

307. *See* Meisel, *supra* note 5, at 451. A discussion of mental disability and the use of surrogates is beyond the scope of this Article.

308. *See* BERG ET AL., *supra* note 197, at 76.

309. Canterbury v. Spence, 464 F.2d 772, 788–89 (D.C. Cir. 1972) (footnotes omitted).

310. *See* Williams v. Payne, 73 F. Supp. 2d 785, 803 (E.D. Mich. 1999); Barnett v. Bachrach, 34 A.2d 626, 629 (D.C. 1943); Curtis v. Jaskey, 759 N.E.2d 962, 967 (Ill. App. Ct. 2001); Moss v. Rishworth, 222 S.W. 225, 226 (Tex. Comm'n App. 1920).

311. *See* Carnahan, *supra* note 29, at 574 ("Presumed consent is based on the presumption that a reasonable person would consent to treatment based on the best judgment of the treating physician."); *see also* Rich, *supra* note 1, at 329.

312. *See supra* note 131 and accompanying text.

resuscitation.[313] Instead, they proceed on the assumption that, if the patient were competent, he or she would consent to the procedures. However, if a patient expressly states that she does not want a certain type or modality of care, the physician cannot use the emergency exception to override her express wishes.[314]

"'Carried to its extreme...the doctrine of implied consent could effectively nullify' an individual's right to refuse medical treatment."[315] As an example, in *Curtis v. Jaskey* a patient brought a battery action against her physician for an episiotomy performed during the patient's labor.[316] The patient had expressly forbidden the physician from performing the procedure.[317] In holding for the patient, the court stated that, "in the face of a clear refusal to submit to a medical procedure, the emergency exception is inapplicable."[318] The court also stated that "a patient can delimit the scope of the relationship, and thus the scope of the physician's duty [to provide care], by withholding consent to particular procedures."[319]

In summary, an exception to informed consent exists when emergency situations require patient treatment. Because patients are often not competent to give consent in these types of situations, informed consent may be presumed. The law assumes that the patient, as a reasonable person, would consent to the care if she was capable of doing so. This presumption is a limited one. The treating physician must heed the patient's express requests, thereby recognizing the value of patient autonomy in the treatment context. While the treatment is given for the good of the individual patient, the patient's wishes are also honored, even if those wishes are against the better judgment of a physician.

2. Emergency Research

An exception to the requirement for informed consent in the research context exists in cases of clinical studies of emergency conditions such as cardiac arrests, strokes, and overdoses.[320] The goal of the exception is to meet the growing need for research by providing researchers with access to otherwise inaccessible subjects for acute care studies.[321] Although there is good reason to presume that people requiring emergency medical treatment would consent to treatment if they could, a similar presumption in the research context is dangerous. While the potential for harm always exists in the sometimes-frenzied situation of emergency treatment, the patient's welfare is the first priority. In contrast, when conducting research during emergency situations, the focus is not on the individual. The special protections in

313. Lindsey Tanner, *Artificial Blood Tested Without Consent*, SYMPATICO HEALTH & FITNESS, Feb. 19, 2004, http://mediresource.sympatico.ca/health_news_detail.asp?channel_id=14&news_id=3402.

314. Curtis v. Jaskey, 759 N.E.2d 962, 967 (Ill. App. Ct. 2001); Shine v. Vega, 709 N.E.2d 58, 65 (Mass. 1999) ("[A] competent patient's refusal to consent to medical treatment cannot be overridden whenever the patient faces a life-threatening situation.").

315. *Curtis*, 759 N.E.2d at 967 (quoting Estate of Leach v. Shapiro, 469 N.E.2d 1047, 1053 (Ohio Ct. App. 1984)).

316. *Id.* at 963.

317. *Id.*

318. *Id.* at 968.

319. *Id.*

320. *See* Marwick, *supra* note 263, at 1392.

321. *See* Susan Alpert, *Taking the Lead*, 6 ACAD. EMERGENCY MED. 1187, 1189 (1999); Carnahan, *supra* note 29, at 568.

research become even more crucial because of the incapacity of the subjects in the emergency research context.

For the emergency research exception to apply, an IRB must find that the researchers have met ten requirements.[322] First, research subjects must be in a life-threatening situation, available treatments must be unproven or unsatisfactory, and collecting scientific evidence must be necessary to determine the safety and effectiveness of the intervention.[323] Second, obtaining informed consent must be impossible because the medical condition prevents the subject from consenting, the timeframe is too narrow to allow for contact of a legally authorized representative, and there is no practical means of prospectively identifying likely candidates for the study.[324] Third, participation in the study must potentially yield a direct benefit to the subject.[325] Fourth, the study could not be completed without the exception.[326] Fifth, the "proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence" and an attempt to obtain consent from a legally authorized representative must be made during this window and documented.[327] Sixth, the IRB must approve of the procedures and documents relating to informed consent from a competent subject or a legally authorized representative.[328] Seventh, the community in which the research will occur must be consulted.[329] The risks and benefits of the study must be made public prior to beginning the research, and the study's results and subject demographics must be made public upon completion.[330] Eighth, if the subject is unable to consent and a legally authorized representative is not available, the researchers must attempt to contact, within the therapeutic window, a family member to determine if there is an objection to enrolling the subject in the study.[331] Ninth, if there is no consent and the subject is enrolled, procedures must exist to inform the subject, a legally authorized representative, or a family member of the subject's enrollment.[332] Any of those three parties may terminate the subject's enrollment at any time.[333] Should the subject die, information on the circumstances surrounding the death must be provided to the representative or family member, if feasible.[334] Finally, the study may not begin until

322. *See* Bateman et al., *supra* note 168, at 1319; Steeves, *supra* note 234 (noting nine requirements); *see also* Carnahan, *supra* note 29, at 565. Carnahan's article includes a thorough discussion of the issues relating to the emergency research exception, including ambiguities that arise from the application of the exception, as well as recommendations to improve its use. *But see* Nino Stocchetti et al., Letter to the Editors, *New European Directive on Clinical Trials*, 361 LANCET 1473 (2003) (discussing how European legislation does not provide for the exception, which creates a concern that patients will be deprived of treatment because of the inability to procure consent).

323. 21 C.F.R. § 50.24(a)(1) (2006); Etchells, *supra* note 13, at 1218.

324. 21 C.F.R. § 50.24(a)(2)(i)–(iii).

325. *Id.* § 50.24(a)(3)(i)–(iii).

326. *Id.* § 50.24(a)(4).

327. *Id.* § 50.24(a)(5).

328. *Id.* § 50.24(a)(6).

329. *Id.* § 50.24(a)(7)(i).

330. *Id.* § 50.24(a)(7)(ii)–(iii).

331. *Id.* § 50.24(a)(7)(v).

332. *Id.* § 50.24(b).

333. *Id.*

334. *Id.*

the FDA grants written authorization to the researchers[335] based on information provided in an application to the FDA.[336] By requiring that these ten conditions be met, the subject who cannot consent to enroll in the study is protected.

Since the regulations were instituted in 1996, the FDA has approved approximately fifteen applications to conduct research using the emergency exception.[337] The first clinical trial to use the exception tested the effectiveness of a drug that is infused during traumatic hemorrhagic shock.[338] To maximize the drug's benefits, infusion must occur within thirty minutes of the trauma.[339] In granting the application under the emergency research exception, the FDA considered "[t]he unpredictable nature of trauma, the severity of illness in the target patient population, and the need to initiate emergency therapy in a brief time period."[340]

Research on the use of prospective informed consent, the consent exception, and consent to continue[341] in the study revealed the following: informed consent or consent to continue was obtained or requested for ninety-one of the ninety-eight patients (ninety-three percent).[342] Seven patients (seven percent) failed to give informed consent or consent to continue.[343] Six patients (six percent) gave prospective informed consent—i.e., consent was given after injury but before treatment.[344] These are powerful statistics because they demonstrate that the granting of consent is not assured. Any presumption about what a subject may or may not do is not necessarily accurate.

The researchers presented a proposed master framework for obtaining consent.[345] Ultimately, however, this framework was not implemented because the sponsor terminated the study early.[346] The framework, however, contained the seeds of an excellent practical program, including the use of a consent exception verification form.[347] The form was designed to document how the exception's requirements were met and to ensure that the exception was used appropriately.[348] The form was to be

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335. 21 C.F.R. § 312.20(c).

336. 21 C.F.R. § 50.24(d).

337. *See* Tanner, *supra* note 313.

338. Edward P. Sloan et al., *The Informed Consent Process and the Use of the Exception to Informed Consent in the Clinical Trial of Diaspirin Cross-linked Hemoglobin (DCLHb) in Severe Traumatic Hemorrhagic Shock*, 6 ACAD. EMERGENCY MED. 1203, 1203–04 (1999).

339. *Id.* at 1204.

340. *Id.* at 1206.

341. *Id.* at 1207 ("The [consent to continue] mechanism offered three options: 1) full continued participation, 2) participation only for safety assessment, or 3) refusal to continue study participation."). Consent to continue is also known as "retroactive consent." *See* British Ass'n for Behavioural & Cognitive Psychotherapies, Guidelines for Good Practice, http://www.babcp.org.uk/joining/good_practice.htm (last visited Nov. 29, 2006).

342. Sloan et al., *supra* note 338, at 1205.

343. *Id.*

344. *See id.* Notably, the study concluded that there was "strong adherence" to the regulations' requirements for informed consent. *Id.* at 1206. Also, the process "met with near uniform approval" by the patients approached to give consent. *Id.* at 1208.

345. Edward P. Sloan et al., *A Proposed Consent Process in Studies That Use an Exception to Informed Consent*, 6 ACAD. EMERGENCY MED. 1283 (1999).

346. *Id.* at 1290. Sloan's article includes a decision tree for obtaining informed consent. *Id.* at 1284.

347. *Id.* at 1290.

348. *Id.*

completed by the researcher, a physician unaffiliated with the study, and a witness.[349]

Not all of the additional protections for subjects under the emergency research exception are effective. One example of this is the need for consultation with the community, which may be problematic for IRBs and researchers.[350] "Community consultation" serves several purposes. Primarily, it exists to provide special protections for vulnerable populations, as well as to obtain informed consent from the community at large.[351] It is, like informed consent, a process.[352] It is not achieved by erecting a billboard or by placing an ad in the newspaper—it is not to be confused with simple public notification.[353] Instead, the investigator must consider the group that the study focuses on and target it accordingly.[354] The FDA rule, however, does not prescribe how to perform community consultation.[355] Instead, researchers are left to construct a process themselves,[356] which can prove problematic when less scrupulous researchers are involved. Commonly recognized methods for obtaining appropriate community consent include holding town meetings, conducting panel discussions with community representatives, and placing community representatives on the IRBs.[357]

There are two essential steps to community consultation.[358] First, the community must be identified.[359] "The ideal community is representative of the patients most likely to be enrolled in the proposed research study."[360] Second, the researchers and the IRB must gather demographic, socioeconomic, and other information regarding

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349. *Id.* ("The regulations require that an independent physician (such as an IRB member) verify that the consent exception is appropriate for the study, but do not require that an independent physician or another witness verify that the consent exception is appropriate for each individual patient....").

350. *See* Charles Marwick, *FDA Gets Feedback on Informed Consent Waiver*, 275 JAMA 347, 347 (1996) ("Manufacturers worried that disclosure might reveal trade secrets, while researchers...noted that ensuring public disclosure could be difficult.").

351. *See* Tanner, *supra* note 313.

352. *See* 21 CFR § 50.24 (a)(7)(i)–(iv) (2004). However, it "does not preempt existing state regulations if waiver of informed consent for research is not allowed." Michelle H. Biros et al., *Implementing the Food and Drug Administration's Final Rule for Waiver of Informed Consent in Certain Emergency Research Circumstances*, 6 ACAD. EMERGENCY MED. 1272, 1274 (1999). This seems logical considering that the purpose behind community consultation is to respect the mores and structure of a community and to overrule a community/state law with a federal regulation would be antithetical to that respect.

353. *See* Biros et al., *supra* note 352, at 1274; Marwick, *supra* note 350, at 347. "We can't help wondering if the institutional review boards [IRBs], sponsors, and researchers are taking the rule seriously, when the only evidence we see of community consultation is an advertisement in the newspaper." Marwick, *supra* note 263, at 1392–93 (alteration in original). Similarly, the Deputy FDA Commissioner related a story involving her local hospital, which "advertised it was conducting a trial of a life-saving emergency therapy, but gave no contact information." Alicia Ault, *FDA May "Pull the Plug" on Consent Waiver*, 350 LANCET 1084, 1084 (1997).

354. *See* Jill M. Baren et al., *An Approach to Community Consultation Prior to Initiating an Emergency Research Study Incorporating a Waiver of Informed Consent*, 6 ACAD. EMERGENCY MED. 1210, 1211 (1999).

355. *See* Ault, *supra* note 353, at 1084.

356. Just as in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. *See supra* Parts III.A.1, III.A.2, III.A.4.

357. *See* Baren et al., *supra* note 354, at 1211. A criticism of the provision is that "the regulations provide no guidelines as to who are 'representatives of the community' from which the subjects will be drawn, nor any explanation of how 'communities' are defined." Carnahan, *supra* note 29, at 582.

358. *See* Baren et al., *supra* note 354, at 1213.

359. *Id.*

360. *Id.* But "[b]ecause the definitions of community differ tremendously from site to site and from project to project, the FDA has not yet provided specific guidelines on how such consultation can be obtained." Biros et al., *supra* note 352, at 1276.

the composition of the community.[361] The information must be sufficient to educate the IRB about the effect of its decision to approve or deny the research study and should include data on distinguishing characteristics of consenting and non-consenting community members.[362]

An analysis of one of the recent programs qualifying for the FDA waiver is illustrative of the process for community consultation. Several years ago, Northfield Laboratories began clinical trials for PolyHeme, an artificial blood substitute to be administered to trauma victims in several major metropolitan areas across the United States.[363] Virtually all citizens were automatically included in the study as a result of the application of the emergency treatment exception to informed consent.[364] Only a few groups were excluded, such as minors, pregnant women, people with terminal injuries, and Jehovah's Witnesses.[365] The exception derives from the fact that, as trauma victims, these patients are incapable of giving consent due to shock and sustained blood loss.[366] Community consultation meetings were held at churches and civic organizations in each community where the trials were to take place in order to educate the community about the study.[367] Northfield Laboratories also advertised the trial on its website, including information regarding the trial's qualification for exception from the informed consent requirements.[368] In this case, it seems that community consultation is continuing successfully.

The same cannot be said for the results of PolyHeme clinical trial results, which are disturbing. Ten of eighty-one patients participating in the initial trial suffered heart attacks within one week of being administered the blood substitute, and two of those ten later died, while all those study participants who did not receive PolyHeme suffered no cardiac events.[369] Yet the FDA continued to allow Northfield Laboratories to test the blood substitute under the emergency exception.[370]

Detractors of the emergency research process are quick to point to the "slippery slope that's essentially demolishing [the] individual right not to become experimental subjects."[371] They emphasize that individual autonomy is severely compromised by implementing the exception via community consultation.[372] But

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361. Baren et al., *supra* note 354, at 1213.

362. *Id.*

363. *See* Northfield Laboratories, Product Description, http://www.northfieldlabs.com/polyheme.html (last visited Oct. 7, 2006); Craig Malisow, *Bloodless Coup*, HOUSTON PRESS, Mar. 4, 2004, at 16, *available at* http://www.houstonpress.com/Issues/2004-03-04/news/news.html.

The results of the first trial generated controversy that continues today, involving Charles Grassley, Chairman of the U.S. Senate Finance Committee, the Office of Human Research Protections, and the FDA. *See* Thomas M. Burton, *Amid Alarm Bells, a Blood Substitute Keeps Pumping*, WALL ST. J., Feb. 22, 2006, at A1; Jeff Nesmith, *Artificial Blood Trial Called Unethical*, COX NEWS SERV., Mar. 19, 2006, http://www.coxwashington.com/news/content/reporters/stories/2006/03/19/BC_ARTIFICIAL_BLOOD19_COX.html.

364. *See* Malisow, *supra* note 363, at 16.

365. *See id.*

366. Nesmith, *supra* note 363.

367. *See* Burton, *supra* note 363, at A1.

368. Northfield Laboratories, PolyHeme Pivotal Phase III Trial, http://www.northfieldlabs.com/amb_trial.htm (last visited Oct. 7, 2006).

369. *See* Burton, *supra* note 363, at A1.

370. Thomas M. Burton, *Blood-Substitute Study Is Criticized by U.S. Agency*, WALL ST. J., Mar. 10, 2006, at A3.

371. *See* Tanner, *supra* note 313.

372. *Id.*

others have responded: "What you do when you want to sacrifice one good to achieve another...is you set up very rigorous review processes to reach a judgment that the one good is worth sacrificing for the other. And you make people justify that."[373] The initial criticism that a slippery slope is created is compelling. The compromise of individual autonomy is terribly significant in this case. By instituting the community consultation provision, one who truly dissents from participation in the study runs a substantial risk of enrollment, regardless of her opinion. And that is wrong.[374]

C. Therapeutic Privilege

1. In the Treatment Context

Therapeutic privilege, inherent in all therapy givers, is a third exception to the requirement of informed consent.[375] The therapeutic privilege permits a physician to withhold harmful information from the patient—even if disclosure of that information would normally be required.[376] The therapeutic privilege conforms to the Hippocratic Oath—an oath that all physicians take requiring them to do no harm to their patients.[377] If the provision of information were to cause harm to the patient, then the Hippocratic Oath would be violated. The exception obviates that possibility.

The landmark case of *Canterbury v. Spence* cautioned that the physician's discretion to withhold information must be carefully limited.[378] This is because "'[a] number of cases appear to have confused the proper relationship of the privilege to informed consent, primarily by allowing the privilege to be used if the patient's subsequent *choice* would be detrimental'" to his health.[379] Instead, *Canterbury* provides for non-disclosure of risk information only.[380] Information on treatment options and benefits are less likely to cause harm to the patient; thus, they receive less scrutiny under the exception than information on potential risks.[381]

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373. *See* Malisow, *supra* note 363, at 17; *see also* Steeves, *supra* note 234 (addressing philosophical arguments for and against the emergency waiver).

374. The response to this criticism is that the dissenter may opt out of the study by the wearing of a wristband indicating his wishes. But it is impractical to wear a wristband for each study in which one does not desire to participate. This places a burden on the individual that does not exist elsewhere. Why should the burden be on the passive citizen? The burden to accommodate the dissenters should be on the party taking the affirmative action—the researchers.

375. *See, e.g.*, Meisel, *supra* note 5, at 460.

376. *See* Canterbury v. Spence, 464 F.2d 772, 789 (D.C. Cir. 1972) ("It is recognized that patients occasionally become so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder the treatment, or perhaps even pose psychological damage to the patient."); Nishi v. Hartwell, 473 P.2d 116, 120, 123 (Haw. 1970), *overruled on other grounds by* Carr v. Strock, 904 P.2d 489 (Haw. 1995).

377. *See* Meisel, *supra* note 5, at 460–61. *See generally* Nancy Rice, Comment, *Informed Consent: The Illusion of Patient Choice*, 23 EMORY L.J. 503 (1974) (analyzing the relationship between therapeutic privilege and informed consent).

378. *Canterbury*, 464 F.2d at 789 ("[For] otherwise it might devour the disclosure rule itself.").

379. *See* Meisel, *supra* note 5, at 461 n.155 (quoting Rice, *supra* note 377, at 506).

380. *Canterbury*, 464 F.2d at 789.

381. *See* Meisel, *supra* note 5, at 464.

2. In the Research Context

The therapeutic privilege is neither appropriate nor recognized in the research context because of the additional information that is required to be provided to research subjects. The privilege should rarely be employed in the treatment context and should never be employed in the case of human experimentation.[382] The therapeutic privilege protects against the provision of the very information that a researcher is required to provide to her subjects—information on potential risks and harm that might arise as a result of the research.[383] Thus, the researcher cannot rely on the therapeutic privilege when conducting research.

D. Waiver

1. In the Treatment Context

The fourth recognized exception is patient waiver of the informed consent requirement.[384] Waiver generally occurs when there is a voluntary and intentional relinquishment of a known right.[385] With the right to informed consent, the focus is on the autonomy of the patient.[386] To ensure autonomy in her decision-making, the patient is entitled to all material information regarding her condition before making a treatment decision.[387] This material information includes notification that caregivers have a duty to disclose information regarding the treatment, that patients have the right to make decisions regarding their treatment, that consent must be given by the patient prior to care commencing, and that patients have the right to consent to, or to refuse care.[388]

Despite the focus on patient autonomy, a huge potential still exists for the physician to exert influence over her patient's decisions. Additional physician duties include conveying accurate information that properly reflects the current condition and situation of the patient.[389] Further, the physician should maintain an awareness of how much influence her words and advice have on her patient.[390] She must remember that a patient who simply requires assistance in decision making is not waiving the right to decide.[391]

Once accurate information is conveyed, patients may waive the right to receive information regarding their care, waive the right to make decisions regarding their care, or both.[392] Patients who waive the right to information but retain decision-making authority are the most challenging for physicians.[393] This challenge

382. *Cf. id.* at 466 ("But where the need for medical care is not urgent, the therapeutic privilege should rarely, if ever, be used.").
383. *See supra* Part I.C.
384. *See, e.g.*, Meisel, *supra* note 5, at 453–60
385. 28 AM. JUR. 2D *Estoppel and Waiver* § 197 (2003).
386. BERG ET AL., *supra* note 197, at 85.
387. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 835 (Md. 2001).
388. BERG ET AL., *supra* note 197, at 85.
389. *See id.* at 86–87 (listing material facts about the nature of the treatment).
390. *Id.* at 88.
391. *Id.*
392. *Id.*
393. *See id.* at 89.

invariably arises because the patient is then making decisions with incomplete information.[394] The physician is faced with implementing a patient's treatment decision that might not be the most effective. To maintain the value of patient autonomy, however, physicians must follow the requests of their patients.

2. In the Research Context

IRBs ensure that proper informed consent is obtained from research subjects.[395] The Code of Federal Regulations provides for the IRB's waiver of the informed consent requirement in situations where the IRB determines that informed consent is unnecessary.[396] To meet the waiver guidelines, the IRB must find that (1) there is only minimal risk to the subjects, (2) waiver of informed consent would have no adverse effect on the subjects, and (3) it is impractical to enact the study without the waiver.[397] If the IRB makes these findings, then it may waive the informed consent requirement for studies falling under its purview.[398]

Waiver of informed consent in the research context is distinguished from the exception to informed consent that exists in the emergency research context. The requirements for waiver are less stringent than for the emergency exception.[399] IRBs may use waiver when there is only minimal risk to the subjects, while the emergency exception is employed only for life-threatening situations.

3. For National Security Purposes

The concept of waiver as it relates to national security has become increasingly important. Informed consent has been, and continues to be, an issue for service members in the U.S. military since World War II.[400] A recent example of this military waiver occurred during the Gulf War. Suits brought after the war by servicemen alleged that the government had failed to obtain their informed consent prior to their exposure to investigational drugs believed to be effective against

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394. *Id.* at 89–90. In these cases, a third party should process information. *Id.*

395. *See supra* Part III.D.

396. *See* 45 C.F.R. § 46.116(d) (2005).

397. *Id.* § 46.116(d)(1)–(4). Specifically, the statute states that

> [a]n IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that: (1) The research involves no more than minimal risks to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Id.

398. For examples of specific documentation that IRBs may commonly require, see Auburn Univ., Waiver of Consent Form by IRB, Auburn University, http://web.archive.org/web/20050210173553/http://www.auburn.edu/research/vpr/ohs/consent/waiver.htm (last visited Jan.. 9, 2007); Univ. of Neb.-Lincoln, IRB Waiver of Informed Consent Investigator Form, http://www.unl.edu/research/orr/Waiver.pdf (last visited Sept. 9, 2006).

399. *See supra* Part IV.B.2.

400. *See* STAFF OF S. COMM. ON VETERANS' AFFAIRS, 103D CONG., IS MILITARY RESEARCH HAZARDOUS TO VETERANS' HEALTH? LESSONS SPANNING HALF A CENTURY (Comm. Print 1994), *available at* http://www.gulfweb.org/bigdoc/rockrep.cfm.

biochemical toxins.[401] The Department of Defense exposed the military members to the drugs based on FDA Rule 23(d), "which allow[ed] the Commissioner of Food and Drugs to waive the informed consent requirement for the use of investigational drugs where certain battlefield or combat-related situations render consent 'not feasible.'"[402]

In *Doe v. Sullivan*, the plaintiff, a serviceman, claimed that the phrase "not feasible" referred to the *capacity* of an individual to give informed consent, and thus Rule 23(d) was violated because informed consent had not been obtained.[403] The FDA, however, contended that the phrase included "impracticable" situations, including "a combat zone setting, the safety of military personnel at that location, and the compelling need to promote success of the service members' mission."[404] The D.C. Circuit Court ultimately held that the military could not be enjoined from the use of investigational drugs on its soldiers without their consent.[405]

Today, servicemen are protected from the administration of investigational or unapproved drugs without the opportunity for informed consent by federal statute.[406] Waiver of informed consent may only be given by the servicemen themselves or the President of the United States.[407] The President may grant a waiver only "when absolutely necessary."[408] A recent suit, *Doe #1 v. Rumsfeld*, resulted from the Defense Department's requirement that servicemen submit to anthrax vaccinations.[409] At the time that the suit was brought, the drug to be administered was not licensed for use as an anthrax vaccination and, thus, the plaintiff contended, was experimental.[410] This use violated 10 U.S.C. § 1107, which prohibits the use of investigational or unapproved new drugs on members of the military without their consent.[411] The Defense Department maintained that obtaining informed consent from every service member would "interfere with the smooth functioning of the military."[412] The federal district court was not persuaded and issued a preliminary

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401. Patrick J. Moran, Comment, *A Military Exception to "Informed Consent":* Doe v. Sullivan, 66 ST. JOHN'S L. REV. 847, 851–53 (1992).

402. *Id.*; *see also* Alicia Ault, *FDA Seeks Comment on Gulf War Waiver*, 350 LANCET 421 (1997).

403. Moran, *supra* note 401, at 858. Clearly the plaintiff's claim was supported by the Code of Federal Regulations. *Id.* at 858 n.59.

404. Doe v. Sullivan, 938 F.2d 1370, 1382 (D.C. Cir. 1991).

405. *Id.* at 1371.

406. Doe #1 v. Rumsfeld, 297 F. Supp. 2d 119, 125 (D.D.C. 2003) (mem.) (citing 10 U.S.C. § 1107 (2000)), *stay granted*, 297 F. Supp. 2d 200 (D.D.C. 2004).

407. *Id.*

> [T]he President may waive the prior consent requirement for the administration of an investigational new drug to a member of the armed forces in connection with the member's participation in a particular military operation....[O]nly the President may waive informed consent in this connection and the President may grant such a waiver only if the President determines in writing that obtaining consent: Is not feasible; is contrary to the best interests of the military member; or is not in the interests of national security.

21 C.F.R. § 50.23(d)(1) (2006).

408. *Doe #1*, 297 F. Supp. 2d at 125 (quoting Exec. Order No. 13,139, 3 C.F.R. 221 (2000), *reprinted in* 10 U.S.C. § 1107 (2000)).

409. *Id.* at 122.

410. *Id.* at 123.

411. *Id.* at 131–32. Put another way, the statute was enacted "to protect soldiers from involuntarily serving as 'guinea pigs' in a mass use of investigational medicine." *Id.* at 134.

412. *Id.*

injunction barring the vaccinations.[413] The court subsequently stayed the injunction because immediately thereafter the FDA categorized the vaccine as safe and effective.[414] The court granted the plaintiff's motion for summary judgment and rejected the FDA's rule based on the fact that the public was not given an opportunity to comment on the FDA's proposed action, as required by FDA regulations.[415] Importantly, as global stability becomes less certain, more men and women may volunteer or be called to serve in the armed forces, making the concept of waiver in the armed forces increasingly important.

V. HIPAA AND RESEARCH

The Health Insurance Portability and Accountability Act (HIPAA) of 1996[416] is designed to protect the health information of patients and research subjects.[417] The Privacy Rule,[418] a regulation promulgated pursuant to HIPAA, outlines the situations where providers and researchers can use protected health information (PHI)[419] and establishes standards for the protection of individually identifiable health information.[420] The goal of the Privacy Rule is to "define and limit the circumstances in which an individual's protected health information may be used or disclosed."[421]

The Privacy Rule, which became effective on April 14, 2003, strikes a balance between the privacy rights of an individual and the need for providers and researchers to use healthcare information.[422] "The Privacy Rule recognizes that the research community has legitimate needs to use, access, and disclose individually identifiable health information to carry out a wide range of health research protocols and projects."[423] "In order for a research subject to give truly 'informed' consent, the subject is entitled to know how their [sic] private information—PHI—will be used in the research study."[424] HIPAA attached a supplemental, separate requirement of

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413. *Id.* at 135. "The [c]ourt is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate." *Id.* at 134.

414. Doe #1 v. Rumsfeld, 297 F. Supp. 2d 200, 200 (D.D.C. 2004). The district court termed the timing of the issuance of the determination "highly suspicious." *Id.*

415. Doe #1 v. Rumsfeld, 341 F. Supp. 2d 1, 19 (D.D.C. 2004), *remanded*, Doe #1 v. Rumsfeld, 172 F. App'x 327 (D.C. Cir. 2006) (per curiam) (holding appeal moot because the FDA passed a rule meeting the district court's requirements).

416. Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 26 U.S.C. and 42 U.S.C.).

417. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH: UNDERSTANDING THE HIPAA PRIVACY RULE at i (2003), *available at* http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf [hereinafter PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH].

418. U.S. DEP'T OF HEALTH & HUMAN SERVS., SUMMARY OF THE HIPAA PRIVACY RULE 1 (2003), *available at* http://www.hhs.gov/ocr/privacysummary.pdf.

419. *Id.* "Covered entities" under the Privacy Rule include "health plans, health care clearinghouses, and any health care provider who transmits health information in electronic form." *Id.* at 2.

420. *Id.* at 1. The Privacy Rule refers to information that can be used to identify an individual as "protected health information." *Id.* at 3–4. This information includes demographic data, as well as information concerning an individual's physical or mental health status, information concerning the provision of health care to the individual, and information regarding payment for the care. *Id.* at 4.

421. *Id.*

422. PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH, *supra* note 417, at i.

423. *Id.* at 2.

424. Univ. of S. Fla., *Can I Include the HIPAA Authorization as Part of the Informed Consent Document?*,

obtaining a subject's consent to use or disclose the subject's PHI used during the study.[425] This notice must be provided to the subject in writing.[426] The regulations permit the use of a "combined form" that covers informed consent for research and authorization for the use of PHI.[427] Organizations, however, are eschewing the use of a combined form because it would require IRBs to review subject authorizations under HIPAA, in addition to their responsibility for ensuring informed consent.[428] HIPAA currently does not empower IRBs to regulate the subject authorizations.[429]

The Privacy Rule functions concurrently with any other state or federal laws and regulations.[430] It serves to supplement the Common Rule such that "some researchers who are also (or who work for) covered entities may find themselves responsible for complying with multiple sets of regulations."[431] It is important to note that the Privacy Rule does not apply to research; rather, it applies to "health plans, health care clearinghouses, and certain health care providers."[432] Thus, the process of research itself is not regulated by the Rule, rather the Rule regulates researchers' access to PHI.[433] Researchers qualify as covered entities if they are health care providers who electronically transmit health information.[434]

The Rule gives individuals the opportunity to sign an authorization form that allows for the use and disclosure of their PHI.[435] The distinction here between

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http://www.research.usf.edu/cs/hipaa_forms/combined.doc (last visited Sept. 11, 2006). The following information must be included in a HIPAA-compliant authorization document:

- A description of the information to be used or disclosed in connection with the research project that identifies the information in a specific and meaningful fashion.
- The name of the person authorized to make the requested use or disclosure.
- The name of the person to whom the requested uses or disclosures may be made.
- A description of each purpose of the requested use or disclosure.
- An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure.
- Signature of the patient/potential subject and date.

Univ. of Mich. Med. Sch., Additional Requirements for Informed Consent Documents Under HIPAA (2003), http://www.med.umich.edu/irbmed/ict/ICD-HIPAA-REQS.pdf (citing 45 C.F.R. §§ 46.116–.117 (2005)).

The following notifications must also be included:

- The patient's right to revoke the authorization in writing.
- Notification of the consequences of refusal to sign the authorization.
- Any information disclosed pursuant to the patient's authorization may be subject to disclosure by the recipient and no longer protected by HIPAA.

Id. Finally, the research subject must be provided with a copy of the signed authorization. *Id.*

425. Univ. of Mich. Med. Sch., *supra* note 424.

426. PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH, *supra* note 417, at 19.

427. *See* Univ. of S. Fla., *supra* note 424.

428. *See id.* "By keeping these two processes separated, the IRB will not be burdened with additional tasks that might detract from their important role in human subject protection." *Id.*

429. *See* Pub. L. 104-191, 110 Stat. 1936 (1996).

430. *See* PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH, *supra* note 417, at 3. "The Privacy Rule does not change current requirements that specify when researchers must submit protocols to the IRB for review and approval, and obtain informed consent documents." *Id.* at 13.

431. *Id.* at 3.

432. 45 C.F.R. § 160.102 (2005).

433. PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH, *supra* note 417, at 5.

434. *Id.* "For example, physicians who conduct clinical studies or administer experimental therapeutics to participants during the course of a study must comply with the Privacy Rule if they meet the HIPAA definition of a covered entity." *Id.*

435. *Id.* at 11. "When an Authorization is obtained for research purposes, the Privacy Rule requires that it pertain only to a specific research study, not to nonspecific research or to future, unspecified projects." *Id.*

authorization and informed consent is that authorization "focuses on privacy risks and states how, why, and to whom the PHI will be used and/or disclosed for research."[436] Informed consent primarily describes the study and its potential risks and benefits. Similar to informed consent, however, the authorization requirement may be waived under certain conditions.[437]

While some federal and state regulations require informed consent to include information on privacy and confidentiality, the Privacy Rule formalizes those requirements. While it does not replace the already existing requirements, it adds a valuable layer that ensures a subject's protection during research studies.

VI. CONCLUSION

Informed consent in the treatment context has a different purpose than in the research context. Treatment is focused on the health of the individual patient, while research is focused on improving the health of society as a whole. Because the focus is not on the individual during research, the potential for injury exists. Because the potential for injury exists, additional protections are necessary for the research subject. While safeguards such as IRBs can provide benefit to the subjects, sometimes they do not function as designed—leaving the research subject without necessary protection. Similarly, exceptions to informed consent are also different in the treatment context than in the research context. The research exceptions again require additional protection for the subjects, such as community consultation. These additional protections for the exceptions do not always function as designed. History has not been kind to researchers who work without the informed consent of their subjects.

The exceptions to informed consent in the treatment context provide direct benefit to the patient. When the health of the patient is at stake, physicians must be allowed to minister to them free from the requirements of informed consent. It is difficult to argue otherwise—thus, the exceptions for informed consent to treatment should stand.

In the research context, however, the focus is primarily on the social benefits of the research, not the individual subject's well-being. As we move further into the age of genomic medicine and designer drugs, the demand for human research subjects will inevitably increase. Similarly, as drugs are able to target a disease with greater specificity, the pool of subjects infected with a specific disease may be smaller. Thus, the demand for the creation of additional exceptions to informed consent will increase to ensure the availability of adequate subject pools. Ultimately these exceptions could swallow the rule, rendering it meaningless and leaving research subjects without protection.[438]

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436. *Id.*

437. *See id.* at 13. The Privacy Rule creates Privacy Boards, analogous to IRBs, to review requests for waiver or alteration of the Authorization requirement. *Id.* Membership composition of Privacy Boards is analogous to that of an IRB. *See id.* Criteria for waiver or alteration are also similar to that for informed consent. There must be no more than a minimal risk to the privacy of an individual, the research could not be practicably conducted without the waiver or alteration, or the research could not be practicably conducted without access to the PHI. *Id.* at 14.

438. To highlight these problems, one group of authors provided a tongue-in-cheek compendium of informed consent statements. These included "[h]uman sacrifice randomised controlled trial consent" and the "[r]andomised

To ensure that the exceptions to informed consent do not swallow the doctrine, limits to the exceptions should be enacted in the research context. Informed consent for research studies should be limited to three categories: (1) informed consent is obtained from the subject; (2) informed consent is obtained from a surrogate or legal representative; and (3) informed consent is not obtained. If the subject falls into the first two categories, then research may proceed. If the subject falls into the third category and informed consent is not obtained, then the subject should be removed from further consideration in the study.

The existing exceptions to informed consent in the research context should be abolished. Some would argue that this will negatively affect research studies by delaying study completion. In the absence of the application of an exception, researchers may lose the subjects who qualify for the study but who cannot enroll because of the lack of informed consent. With the abolition of these exceptions, the research study's enrollment period would increase because the present exceptions would not apply to facilitate the enrollment of subjects in the studies. The research, however, would eventually still proceed. A lengthier enrollment period will compromise no one and likely will not affect the research itself. Further, individual autonomy, the most precious of values, remains respected. The right to control one's own body is not infringed upon by instituting these exceptions. Physicians and researchers, or patients and subjects, would be free to move medicine and science forward at no individual's expense.

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controlled trial consent for stockholding investigators." Andrew Oxman et al., *A Practical Guide to Informed Consent to Treatment*, 323 BRITISH MED. J. 1464, 1464 (2001). While clearly a satirical view, the article nevertheless casts an interesting light on differing views of the informed consent process.