For more than thirty years, federal regulations—collectively known as the "Common Rule"—have governed all federally funded medical research involving human subjects. The Common Rule requires, inter alia, that any research facility receiving federal funds submit a Federal Wide Assurance (FWA) to the department or agency from which funding is sought. The FWA is a contract in which the research facility promises to abide by the Common Rule for all of its research that involves human subjects, whether it is privately or federally funded. Drawing upon other instances in which third-party beneficiaries have successfully enforced government contracts, this Note argues that, upon discovery that a contract of assurance has been breached in the course of federally or privately funded research, a research subject should be able to maintain an action against the research institution as a third-party beneficiary to that contract.

Introduction

In April 2001, Ellen Roche—a healthy, twenty-four year-old woman—volunteered to participate in an asthma study conducted by the Johns Hopkins Asthma and Allergy Center, where she worked as a technician. In exchange for $365, she agreed to inhale a "medication that . . . stopp[ed] some nerves in [her] airways from functioning for a short period" in order to test a hypothesis about the workings of asthma. Although one of the two previous test subjects had experienced shortness of breath and developed a cough after inhaling the solution, the researchers continued the study. Ellen was hospitalized five days after her initial inhalation, and she died twenty-four days later. Investigations into Ellen's death later revealed that the researchers had disregarded many of the federal rules designed to protect vulnerable research subjects like her. These violations included the researchers' failure to tell the body overseeing their actions of the prior subject's problem until after Ellen was hospitalized; the director of the study's failure to account for literature showing that the substance administered could have pulmonary toxic effects; and failure to disclose to potential research subjects that the substance administered was not approved by the Food and Drug Administration (FDA).

Unfortunately, accounts like Ellen's have become all too common. Yet, for over thirty years, federal administrative regulations have governed all federally funded medical research involving human subjects. These regulations, known as the "Common Rule," have their genesis in prior international codes designed to protect human research subjects and apply to research sponsored by sixteen federal agencies and departments of the United States government, including the Department of Health and Human Services (DHHS). In exchange for federal funding from one of these agencies, a research facility must submit a Federal Wide Assurance (FWA) to the department or agency from which funding is sought. The FWA is a contract in which the research facility promises to abide by the Common Rule for all of its research that involves human subjects, whether it is privately or federally funded.
a research subject should be able to maintain an action against the research institution as a third-party beneficiary to that contract. Part I sets forth background on the development of human subject protections, describes the requirements of the Common Rule, and examines several reasons why the current regulatory framework for the protection of human subjects in the United States has proved inadequate. Part II discusses obstacles that potential plaintiffs face when suing in tort and argues that a contract remedy would add a valuable tool to an injured research subject's legal arsenal. Part III sets forth the law of third-party beneficiary contracts and considers other contexts in which courts have been willing to allow third parties to enforce contracts of assurance between the federal government and a state or private entity that is the recipient of federal funding. [FN9] Part IV analogizes from other instances in which third-party beneficiaries have successfully enforced government contracts, concludes that research subjects have standing as third-party beneficiaries to the contracts between research institutions and the federal agencies from which those institutions receive funding, and then examines the advantages and disadvantages of pursuing such a legal strategy.

I. Government Regulation of Research Using Human Subjects

Despite the more than thirty-year-old elaborate federal regulatory process governing the approval and review of research using human subjects, the need for additional protection--in the form of incentives for compliance--is readily apparent. As the dean of the Johns Hopkins University School of Medicine recently stated, "At a certain point, some patient is going to die in clinical trials. There is no question about it." [FN10] Given this certainty, one would expect researchers using human subjects to exercise the utmost caution, in order to decrease the risk of harm or death to their subjects.Sadly, this has not been the case; horrific stories of error and abuse in research involving human subjects in the United States continue to surface. In fact, in this country and others, the development of regulations governing research with human subjects has usually followed closely on the heels of highly publicized research abuses. [FN11] The history of research involving human subjects has been described by ethicists as one of "progress propelled by scandal." [FN12] This Part details the history and requirements of the Common Rule and explains why, in practice, the Common Rule has not provided adequate protection for human research subjects. [FN13]

A. The History of the Common Rule

The federal regulations that currently govern federally funded research involving human subjects have their origins in two international codes: the Nuremberg Code [FN14] and the Declaration of Helsinki. [FN15] The Nuremberg Code, which has been called "the most important document in the history of the ethics of medical research," [FN16] was created in 1947 in reaction to grossly unethical experimentation by Nazi physicians during World War II [FN17] and "revelations about nonconsensual human experimentation" in the United States. [FN18] It contains a "set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners." [FN19] Some fifteen years later, the World Medical Association drafted the Declaration of Helsinki, which has been described as "the fundamental document in the field of ethics in biomedical research." [FN20] The Declaration was drafted in part as an alternative to the Nuremberg Code, which dealt exclusively with nontherapeutic research. [FN21] It sets forth a number of principles intended to govern the relationship between research subjects and researchers. [FN22] The World Medical Association adopted the Declaration of Helsinki in 1964, following a series of scandals involving grossly unethical experimentation on human subjects. [FN23]

The first policies regarding research with human subjects in the United States were internal to the National Institutes of Health. [FN24] These policies were eventually codified in the form of federal regulations issued by the Department of Health, Education, and Welfare (now the Department of Health and Human Services) in 1974. [FN25] Later that year, Congress passed the National Research Act (the Act), [FN26] largely in response to another scandal: the Tuskegee Syphilis Study, in which hundreds of African American men who had been diagnosed with syphilis were left untreated for nearly
thirty years so that government researchers could study the progression of the disease. [FN28] The Act established the Office for the Protection of Research Risks (OPRR) [FN29] within the National Institutes of Health (NIH) and established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Commission), [FN30] which was meant to study the problems attendant to *898 human-subject research and then propose guidelines for the protection of subjects. [FN31]

In 1978, the Commission released the Belmont Report (the Report), [FN32] which sets forth basic ethical principles for research involving human subjects: respect for persons, [FN33] beneficence, [FN34] and justice. [FN35] The Report also translates these aspirational ethical principles into "moral requirements" that are meant to guide researchers on a daily basis. The principle of respect for persons, embodied in the Report's requirement of informed consent, [FN36] mandates "that subjects enter into research voluntarily and with adequate information." [FN37] At a minimum, informed consent requires that a potential subject be given "sufficient" information and that the subject "adequately comprehend[ ]" this information prior to his or her decision to participate in the research. [FN38] The principle of beneficence mandates that the potential risks to research subjects be carefully weighed against the potential benefits to society and that research proceed only if this risk/benefit assessment is "favorable." [FN39] The principle of justice mandates that research subjects be selected in a fair and equitable manner. [FN40] Researchers must ensure that all persons have an equal chance to participate in potentially beneficial research and distinguish between those subjects who should and those who should not participate in a given type of research. [FN41]

The Report led DHHS to revise its regulations significantly. [FN42] In 1991, those regulations--also known as the Common Rule--were separately *899 adopted by fifteen other federal agencies. [FN43] The Common Rule now governs all human subjects research that is sponsored by any one of those federal agencies. [FN44]

B. The Requirements of the Common Rule

1. Assurances.--The Office for Human Research Protections (OHRP) [FN45] is responsible for implementing the Common Rule and for providing guidance on ethical issues in all federally sponsored or federally affiliated biomedical research. [FN46] The Common Rule currently requires that any institution that conducts federally funded human-subject research [FN47] submit to the department or agency sponsoring that research a written assurance that its researchers will comply with all of the requirements of the Common Rule. [FN48] Until December 2001, the OHRP approved three types of assurances: Single Project Assurances (SPAs), which apply to a single research activity at a single location; Multiple Project Assurances (MPAs), which cover multiple--often unrelated--research activities at a single location; and Cooperative Project Assurances (CPAs), which cover multiple research activities at multiple locations. [FN49] Beginning in December 2001, however, the OHRP made available a new type of assurance: the Federal Wide Assurance (FWA). [FN50] FWAs are designed to streamline the research-approval process by allowing a research institution with a valid FWA on file with the OHRP to receive funds from any department or agency that subscribes to the Common Rule without filing any additional assurances. [FN51] SPAs, MPAs, and CPAs are replaced with FWAs as the former expire; all existing assurances must be superseded by FWAs no later than December 31, 2003. [FN52]

The Common Rule specifies the elements of a valid assurance. [FN53] Each research institution must develop and promise to follow a "statement of principles . . . in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation." [FN54] Thus, in exchange for receiving federal funds for some of its research, an institution agrees to comply with the ethical requirements of either the Belmont Report or a similar set of ethical principles acceptable to OHRP for all of its research--whether privately or federally funded. [FN55]
2. Institutional Review Boards.--The Common Rule also mandates that all research institutions that receive federal funds for research using human subjects establish one or more Institutional Review Boards (IRBs), consisting of at least five members, to oversee all human subject research. [FN56] An institution's assurance must designate the IRB applicable to a given research protocol, [FN57] include a written list of the IRB's members, [FN58] and describe the procedures that the IRB will follow in discharging its duties. [FN59]

Before approving a research protocol, an IRB must consider six factors: the risks involved, the adequacy of informed consent, equity, privacy, the vulnerability of the human subjects who will likely participate, and any inappropriate incentives. [FN60] Thus, prior to approving a protocol, an IRB must determine that, among other things, the risks to subjects are minimized and reasonable in relation to the anticipated benefits, the selection of subjects is equitable, and informed consent will be sought and documented in accordance with the applicable regulations. [FN61] IRBs are also responsible for continual review of research as it is carried out, [FN62] and they must keep detailed records of their actions. [FN63]

3. Informed Consent.--The Common Rule also explicitly mandates, as does the Belmont Report, that each subject provide informed consent before being allowed to participate in any research. The general requirements for valid informed consent are quite lengthy; [FN64] they include, inter alia, a duty on the part of researchers to disclose the experimental nature of the study and to describe the purposes of the research, the potential or anticipated benefits-- if any--to the subject or third parties, and "any reasonably foreseeable risks or discomforts to the subject." [FN65]

C. Are Human Research Subjects Adequately Protected?

Recently, medical research involving human subjects has come under intense scrutiny. [FN66] For example, the highly publicized death of Jesse Gelsinger, a research subject who died as a result of his participation in a gene therapy trial at the University of Pennsylvania, aroused significant media attention and public concern regarding the safety of clinical trials. [FN67] His story is far from unique, and both endogenous and exogenous pressures for reform are mounting. [FN68] Medical research suffered another blow in the eyes of the public when it was discovered that researchers and pharmaceutical companies involved in research at Cornell and Tufts Universities had failed to notify the National Institutes of Health that six gene therapy research subjects had died during experiments over a nineteen-month period. [FN69] The issues that have been the most hotly debated in light of these recent failures include the adequacy of informed consent of research subjects, the surveillance of research protocols by IRBs, the failure of IRBs to report adverse events, [FN70] and researchers' potential conflicts of interest. [FN71]

*903 The Common Rule itself is not without flaws. The concepts of minimal risk and informed consent are meant to be the cornerstones of the federal regulations designed to protect the rights, welfare, and integrity of the individual in the course of research. Yet the principle of consent--clearly and unequivocally articulated in the Nuremberg Code, on which the Common Rule is based--is "diluted and deemphasized in later codes and in the U.S. federal regulations." [FN72] Current trends in research and its regulation continue to erode the requirement of consent, [FN73] while the level of acceptable risk has been elevated to the extent that some have described the concept of minimal risk as being "upwardly mobile." [FN74] This shift from the underlying ethical framework of the Nuremberg Code and the Declaration of Helsinki does not bode well for research subjects, particularly in the modern age of genetic research. [FN75]

1. The Changing Landscape of Medical Research.--The question of why the current system of human-subject protection--particularly the oversight of IRBs--has become so glaringly inadequate is a difficult one to answer. It is clear, however, that many recent failures can be attributed to the changing nature of medical research. Specifically, medical research has undergone a fundamental paradigm shift for which the IRB is arguably ill-equipped.
a. The Inherent Weakness of IRBs.--The efficacy of the current protections of human research subjects requires proper monitoring of research protocols by IRBs. Over the three decades since the promulgation of the Common Rule, however, research involving human subjects has grown exponentially and now exceeds the monitoring capabilities of existing IRBs. Indeed, due in part to increased corporate sponsorship of research, in the last decade the average IRB has gone from reviewing approximately forty protocols per year to reviewing more than three hundred. At the time of the Common Rule's inception, medical research typically involved a single researcher at a single institution, but the research landscape has changed dramatically over the past decade. Research protocols are now often conducted at many different locations simultaneously and involve large numbers of researchers and research subjects.

This emergence of large, multicenter--sometimes international--clinical trials, coupled with an increase in funding (and a shift from primarily government to primarily corporate sponsorship) has "made apparent the inadequacy of mechanisms for protecting patient-subjects"--mechanisms that were developed during a period when clinical research was much simpler and conducted on a much smaller scale. This has caused many people--from both inside and outside the medical research community--to conclude that existing IRBs are simply not equipped to handle these multisite trials. Due to recent, highly publicized fatalities, IRBs have come under increasing pressure to perform their role as the official watchdogs of research involving human subjects.

Moreover, although the regulations have been supplemented over the years, institutional support given to IRBs is often minimal. As early as June 1998, the Office of the Inspector General of DHHS issued four investigative reports that concluded that IRBs had excessive workloads and inadequate resources. IRB oversight at several institutions was described as "inadequate," and DHHS also found that, on occasion, researchers were not providing the IRBs with enough information to allow them to evaluate clinical trials effectively. All of these factors combine to create a dangerous situation for research subjects.

b. A Fundamental Paradigm Shift in Medical Research.--The inherent weakness of IRBs has become particularly salient of late, as medical research in the past two decades has undergone a fundamental paradigm shift from primarily nontherapeutic research (i.e., research that promises no therapeutic benefit to the subject) to primarily therapeutic research (i.e., research that purports to provide a therapeutic benefit to the subject). The earliest protections for subjects of medical experimentation emphasized the risks and burdens of research and the consequent need to protect potential and actual research subjects from abuse and exploitation. The ethical guidelines for this type of research, therefore, focused on ensuring that subjects gave voluntary and informed consent.

As the medical community’s focus has shifted from nontherapeutic research to therapeutic research, there has been a corresponding shift away from the traditional, paternalistic view of research ethics toward a view that emphasizes access. Because modern medical research may offer the best hope for a cure to the sufferers of debilitating or fatal conditions, it is crucial that these therapies, although experimental, are available to as many people as possible. The emerging access-centered model of ethics reflects the medical community’s desire to ensure that all people have equal access to potentially lifesaving therapies, regardless of race, nationality, or wealth. For example, clinical trials of new therapeutic agents--such as new drugs to combat HIV and AIDS--have resulted in a move toward an access-centered model of research ethics. This increased focus on inclusion may be partially responsible for abandonment of the essential aspects of the protectionist model that guarantee subjects' privacy and safety.

2. Other Pressures to Weaken Protections.--In addition to the larger systematic pressures discussed above, there are many other reasons why human subject protections have become weaker in recent years. Indeed, the rapid advancement of science
is itself a source of pressure to weaken protections for human subjects. Times of great technological achievement are rarely accompanied by self-imposed restraint, and this is unquestionably a time of great technological achievement for medical research. Due to the dramatic increase in the funds available for medical research, the vastly improved capabilities of computers, and the fruits of earlier experimentation, medical research has progressed dramatically during the last two decades.

Conflicts of interest are another source of pressure on the system of protection. [FN94] The sharp increase in privately funded (i.e., industry sponsored) research has created an atmosphere that breeds conflicts arising from compelling financial incentives. [FN95] These conflicts may arise from researchers' financial relationships with companies whose products they are studying, whether the research is sponsored by the government or by the company itself. Critics have declared that academic researchers are "for sale," [FN96] that their engagement in clinical research can be bought or bartered, and that the outcome of research is thus biased by academic-*907 industrial alliances--whether those alliances are personal to the researcher or institutional. [FN97]

One example of the result of such conflicts was revealed in a disturbing report of inappropriate subject-recruitment practices. The report, which was issued by the Office of the Inspector General of DHHS in February 2000, [FN98] focused on studies funded by drug companies [FN99]-- including one "case of a woman in a nursing home who was allegedly forced to participate in a study under threat of expulsion from the home." [FN100] The report noted that aggressive recruiting by researchers who have been offered money or other inducements might be contributing to the erosion of informed consent. As researchers are pressured to recruit subjects quickly in order to discover the next big pharmacological miracle, they may misrepresent the true nature of a trial--appealing to subjects' trust. [FN101]

3. Deliberate Failure to Follow Proper Procedures.--In addition to these weaknesses in the current framework for the protection of human research subjects, there is mounting evidence that many researchers do not adhere to standards of good clinical practice, much less the more aspirational ethical guidelines of the Common Rule. Even if the Common Rule and the IRB system were perfect, incompetence or intentional ethical lapses in the zealous pursuit of advances in science or financial gain by individual researchers or teams of researchers would still be problematic. For example, the FDA has identified cases in which researchers failed to *908 disqualify subjects who did not meet the criteria for a study, failed to report adverse events as required, flouted protocol, and ignored inadequacies in the staff's training. [FN102] These were not isolated instances; these problems, among others, have occurred at some of the nation's best-known and most prestigious research centers, in some instances implicating "leaders in their fields of study." [FN103]

a. The Jesse Gelsinger Case.--On September 17, 1999, an eighteen year-old college student named Jesse Gelsinger died while participating in research conducted by the University of Pennsylvania's Institute for Gene Therapy. [FN104] Jesse volunteered for a clinical trial of a new treatment for ornithine transcarbamylase (OTC) deficiency, a rare metabolic disorder that affects the body's ability to metabolize ammonia. [FN105] The severity of OTC varies widely from patient to patient; Jesse "suffered from a relatively mild form" [FN106] of the disease, which was controlled with a low-protein diet and medication. [FN107] The clinical trial in which Jesse participated used a strain of the common cold virus as a "viral vector" to transport new genetic material directly to the subject's liver. [FN108] Jesse was injected with the viral vector on September 13, 1999, after which he suffered from a host of serious complications, including a blood-clotting disorder, kidney failure, lung failure, and, ultimately, brain death. [FN109] Investigation of Jesse's death revealed that he had not been an appropriate candidate for the study [FN110] and that information regarding the severe adverse reactions of other participants had been withheld. [FN111] This gross deviation from the standards set forth in the Common Rule resulted in the suspension of the *909 University's gene therapy program. [FN112] The Gelsinger family filed suit soon after Jesse's death. A settlement agreement, the details of which have not been publicly disclosed, was reached on November 3, 2000. [FN113]
II. Obstacles to Recovery in Tort

The inadequacy of the existing protections of human research subjects is particularly alarming because injured research subjects often lack the incentive to seek redress for their injuries in the courts. Because the Common Rule does not expressly establish a private right of action for injured research subjects, [FN114] they have had to resort to state tort law, which presents more obstacles than most plaintiffs are willing to navigate--especially if their injuries are minor. [FN115] To further complicate matters, case law interpreting--or even addressing--the Common Rule is almost nonexistent. [FN116]

A. Negligence

At first glance, a negligence action might appear sufficient to compensate injured research subjects and deter unethical research practices. In fact, injured research subjects have recovered via negligence actions--or at least the settlement of negligence actions. [FN117] There are various theories upon which a negligence action against offending researchers, research institutions, or IRBs could be based. [FN118] In all cases the injured plaintiff would have to prove the basic elements of a negligence cause of action: that the defendant owed a duty of care to the plaintiff; that the defendant breached that duty; that the defendant's breach caused injury to the plaintiff; and that the plaintiff suffered actual damages from that injury. [FN119] Depending on the situation, injured research subjects could have a great deal of difficulty proving any one of these elements.

The threshold question in any negligence action is whether the defendant owed a duty of care to the plaintiff. Although the existence of a duty can be established via government regulations, [FN120] only one court has found that the Common Rule as codified at 45 C.F.R. section 46 imposes a duty on the part of researchers, research institutions, or IRBs. In Grimes v. Kennedy Kreiger Institute, Inc., [FN121] young children who participated in a nontherapeutic research study funded in part by the Environmental Protection Agency (EPA) sued the research institution for negligence based on alleged violations of the standards set forth in the Common Rule. The stated purpose of the research was to study the effectiveness of various partial lead-paint abatement procedures in order to find a level of decontamination that would be relatively safe but economical enough so that landlords would not abandon their low-income housing units. [FN122] In order to measure the effectiveness of particular abatement methods, researchers measured the presence of lead in the blood of healthy children. Poor families with very young children (preferably between five and eighteen *911 months old) were "recruited" to live in test houses in which lead paint had been abated--but not eliminated--using one of the methods under investigation for the purpose of measuring the level of lead present in these children over a period of time. [FN123]

The plaintiff alleged inadequacy of informed consent, improper solicitation of subjects, and greater than minimal risk to children in a nontherapeutic study. [FN124] Reversing the lower court's grant of summary judgment in favor of the defendants, the Court of Appeals held, inter alia, that federal regulations (i.e., the Common Rule) created a legally cognizable duty to human subjects on the part of researchers that arose out of the unique researcher-subject relationship, [FN125] the breach of which may constitute negligence. [FN126] Although the Grimes court found that the Common Rule established a legal duty, no subsequent court has followed suit. Moreover, the Grimes court seems to have confined its opinion to the context of nontherapeutic research. [FN127] Grimes should, therefore, be viewed as an aberration, rather than as the heralding of a new judicial approach to actions brought by injured research subjects.

In fact, even if courts were willing to treat a breach of the Common Rule as tantamount to negligence per se, [FN128] this would not ensure recovery for plaintiffs. As the Grimes court concedes, even plaintiffs who are clearly wronged will not recover unless they can demonstrate that they have suffered a cognizable injury as a result of the breach. [FN129] Moreover, determining the appropriate standard of care in the research setting may be problematic. Although the Common Rule arguably sets forth a standard of care, it is unclear whether--or even how--a court would apply it against all possible
defendants, given the wide range of responsibilities and capabilities of the many people involved in a research protocol. [FN130]

Consider a lawsuit brought against a research institution for an IRB's negligent approval of a protocol. [FN131] Like any entity that undertakes a special duty to protect others, an IRB would be negligent if it approved a protocol that a reasonable IRB in its position would have rejected. [FN132] Whether the IRB had strictly complied with the Common Rule would, of course, be relevant to the inquiry. But the Common Rule itself requires that the members of an IRB be drawn from diverse areas of expertise--both scientific and nonscientific. Given this directive, it seems unlikely that a court would interpret the Common Rule as imposing a single, fixed standard of care upon all IRB members. Instead, it would likely be construed as imposing something of a sliding standard, which would vary based upon each IRB member's particular background. The plaintiff might be forced to establish a standard of care and its breach, with respect to each member of the IRB. This would be a difficult, time-consuming, and expensive proposition.

Causation and damages--the final two elements of a negligence action--create special difficulties in the context of human research subjects. With regard to causation, it is often impossible to know whether the defendant caused a subject's injury. In many cases, the only thing that can be known is that a researcher, research institution, or IRB breached the federal regulations designed to safeguard human subjects; any damage caused by that breach could lay dormant for many years. In addition, it may be particularly difficult for subjects of therapeutic research, who received experimental treatments for preexisting physical or psychological ailments, to establish proximate causation and damages. [FN133]

B. Other Avenues of Recovery

Other possible bases for lawsuits brought by research subjects include invasion of privacy, breach of a duty of confidentiality, or--in the context of research involving physically invasive procedures--trespass or medical battery. [FN134] Long before the advent of IRBs, the leading case in the area of medical battery was Bonner v. Moran. [FN135] in which a child sued doctors who had tried to transfer skin from him to his burned cousin without his mother's consent. [FN136] Although Bonner did not involve research, it provides a nice analogy to nontherapeutic research, because it involved medical intervention from which the patient-plaintiff would not directly benefit. [FN137] The court held that, although children may sometimes give effective informed consent to treatment when they stand to benefit directly, this principle did not apply where the treatment was to benefit someone else. The physician's liability was, therefore, predicated on his failure to obtain parental consent. [FN138] Much more recently, in Grimes, the Maryland Court of Appeals held that even parental consent is ineffective in the context of nontherapeutic research that poses more than a minimal risk to a minor child. [FN139]

In the context of behavioral or social science research, a subject might recover if she suffered some sort of mental injury as a proximate result of the researchers' negligence in conducting the experiment. [FN140] In addition, recovery based on breach of confidentiality would be possible if information revealed for the purposes of research was leaked and the plaintiff suffered injury as a result (loss of employment, for example). [FN142]

*914 Each of the causes of action discussed above is highly speculative and presents difficult obstacles that plaintiffs must surmount before any recovery is possible. The next Part will consider whether injured research subjects should be able to bring a cause of action sounding in contract.

III. A Cause of Action Sounding in Contract

This Part describes the law of third-party beneficiary contracts and considers other contexts in which courts have been willing to allow third parties to enforce contracts of assurance between the federal government and a state or private entity that is the recipient of federal funding. In general, there are three ways in which persons who are not parties to, but benefit from, a
federal contract can seek redress upon breach of contract. First, such persons can—and often must—pursue any available administrative remedies before seeking judicial review. Second, such persons may be able to assert a private right of action based on the statute that authorized the contract. In recent years, however, the Supreme Court has become increasingly reluctant to recognize such implied rights of action. Third, such persons may be able to assert standing as third-party beneficiaries of the contract between the government and the breaching party. A significant number of third-party beneficiary claims have been brought in the context of welfare-related public contracts; but courts have often denied third-party beneficiary standing in cases where one would expect the opposite result. Some commentators have suggested that this reveals a failure on the part of courts to disaggregate congressional intent and a consequent failure to distinguish between implied rights of action and third-party standing.

A. Third-Party Beneficiary Doctrine

In general, a third-party beneficiary contract is an agreement under which the promisor, in exchange for something from the promisee, agrees to render his performance for the benefit of a third party, who can enforce the contract. Recognition of this right of a third party to enforce a contract is something of an anomaly, inasmuch as it allows a party who has neither given consideration to, nor been in privity with, either of the contracting parties to maintain an action to enforce the contract, irrespective of whether that third party had contemporaneous knowledge of the contract's formation. This is an exception to the traditional assumptions of common law contract doctrine and has, since its inception, resulted in inconsistency among the courts as to both analyses and outcomes.

In determining whether a plaintiff has standing as a third-party beneficiary, many courts have incorporated the test set forth in the Restatement (Second) of Contracts. The Restatement's formulation of third-party beneficiary standing turns primarily on intent. Section 302 of the Restatement categorizes beneficiaries of a contract as either "intended" or "incidental" beneficiaries: "Intended beneficiaries" may enforce contracts, while "incidental beneficiaries" may not. Intended beneficiaries are defined by the Restatement as follows:

(a) the performance of the promise will satisfy an obligation of the promisee to pay money to the beneficiary; or

(b) the circumstances indicate that the promisee intends to give the beneficiary the benefit of the promised performance.

The third-party enforcer must point to circumstances showing that the promisee had an independent intention that the third party would receive the benefit of the performance. The third-party plaintiff does not have to prove that the promisee intended that the plaintiff have a right of enforcement--only that the promisee intended that the plaintiff "receive the benefit of the promise."

Courts have developed two variations on the test for whether a plaintiff has standing as a third-party beneficiary to a contract. The first applies to private contracts; the second to public and government contracts. In the context of private contracts, section 302 of the Restatement is applied as written. Government contract cases, however, raise special difficulties for the determination of beneficiary rights. Because every member of the public at large could potentially be considered an intended beneficiary of most government contracts, a more restrictive test for third-party beneficiary status is used, usually the test set forth in section 313 of the Restatement. Section 313(1) adopts the general rules of third-party beneficiary enforcement from section 302 (including the "intent" test), while section 313(2) addresses the particular analytic problem presented by government contracts: how to differentiate among the many...
possible "beneficiaries" and determine who--if anyone--has enforcement rights. [FN164] Section 313(2), when read in conjunction with section 302, [FN165] grants third-party beneficiary rights in the context of a government contract only if the promisee both intended to benefit the third party and intended to confer to that third party a right to enforce that benefit. [FN166]

Courts have not consistently adopted the Restatement formulation; many courts have focused solely on intent to benefit, [FN167] while other courts--following section 313(2) more closely--have searched for an intent to grant standing to enforce the benefit, whether express or implied. [FN168] At least one commentator has argued that beneficiary rights to government contracts should be determined by measuring the "impact of an additional remedy" on the objectives of the relevant statute, [FN169] while others have proposed that the intent to benefit test be abandoned in favor of a test that measures "justifiable reliance" by the beneficiary in light of the surrounding commercial and social circumstances. [FN170] In addition, reliance has come to play a larger role in contract law of late, including in the courts' analyses of third-party beneficiary contract law. [FN171]

*918 B. Third-Party Enforcement of Government Contracts of Assurance

Because of the frequency with which the government employs contracts as instruments of federal policy, recent years have been marked by a wave of cases involving third-party beneficiary claims under contracts with agencies of the federal government. [FN172] A contract of assurance is created when a statute authorizes federal funding for a specific purpose, in exchange for the recipient's promise to further that purpose in some way. [FN173] This type of arrangement has been used in the past in the context of hiring handicapped individuals pursuant to the Rehabilitation Act of 1973, [FN174] compliance with Medicare regulations, [FN175] and admission of African American children to desegregated public school systems pursuant to Title VI of the Civil Rights Act of 1964. [FN176]

The Supreme Court has explicitly endorsed third-party beneficiary enforcement of contracts of assurance. In Lau v. Nichols, for example, the Court held that because a school district had contractually agreed to comply with standards promulgated by the Department of Health, Education, and Welfare (DHEW), a plaintiff class consisting of approximately two thousand non-English speaking children of Chinese ancestry enrolled in the San Francisco public schools was entitled to enforce DHEW's regulations and guidelines requiring school districts to take "affirmative steps" to rectify language deficiencies. [FN177]

Further guidance on this issue may be gleaned from the Fifth Circuit's opinion in Bossier Parish School Board v. Lemon. [FN178] In Bossier, the court held that the children of African American personnel at an Air Force base were intended beneficiaries of a funding contract between the United States and the local school district. [FN179] The contract at issue in that case required the school district to admit those children to "white" schools in accordance with Title VI, in exchange for financial aid. [FN180] As Professor Farnsworth points out, however, the claim in Bossier may have had "particular appeal because, had it been denied, the school board would have been left with funds for which it had not rendered its promised performance." [FN181] Courts have not, however, consistently required that there be an element of unjust enrichment in order to prevail in a case such as this. [FN182]

Although there are exceptions, courts have generally been quite willing to analyze contracts according to the third-party beneficiary doctrine. [FN183] In decisions to the contrary, "[t]he most common reason given for rejecting the claim is not that the doctrine is inapplicable, but rather that the contracting parties did not intend to create a class of third party beneficiaries." [FN184]

IV. Research Subjects Are Third-Party Beneficiaries with Enforcement Rights
As shown above, existing law provides substantial support for the proposition that aggrieved persons can recover as third-party beneficiaries to contracts of assurance between a federal sponsor of research and a research institution. These contracts explicitly require the research institution to comply with the Common Rule in all research conducted at the institution, whether privately or federally funded. This Part demonstrates that human research subjects are intended beneficiaries of these assurances, are a well-defined class, and that private enforcement of these contracts is entirely consistent with the goals of the Common Rule.

A. Assurances as Third-Party Beneficiary Contracts

There can be no dispute that the assurances entered into between federal agencies or departments and research facilities that conduct federally funded research are legally binding contracts in every sense of the term. Section 46.103 of the Common Rule, which describes these contracts, states that:

Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. . . . Assurances applicable to federally supported or conducted research shall at a minimum include: (1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation.

Section 46.122 reiterates the requirements of section 46.103, clearly indicating that federal funding is conditioned upon compliance with the Common Rule (for federally funded research) and compliance in the course of all research with "principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research" that are set forth in each institution's assurance.

What might not be obvious from a cursory glance at this provision is that nothing explicitly requires an institution to agree to abide by every provision of the Common Rule in the course of privately sponsored research. In fact, many assurances exempt an institution from one or more of the Common Rule's requirements. But this flexibility does not mean that these assurances are "voluntary" or illusory. There is nothing illusory about the agreement between the federal agency or department and the research facility. Once the exemptions to the Common Rule for privately funded research have been proposed and agreed upon by the parties, the assurance is a contract, complete with consideration and mutual assent. Indeed, under the Common Rule, a material breach of the research facility's obligations--if discovered--may result in termination of financial support.

Thus, federal funding is contingent upon the recipient's adherence to the Common Rule, and it is also consideration for the recipient's promise to abide by the agreed-upon standards for the protection of research subjects (i.e., the Common Rule, possibly with exemptions) involved in any of its research.

B. Enforcement Rights of Research Subjects

Assuming that the assurances are contracts, the question remains whether human research subjects are intended beneficiaries of those contracts. It could not seriously be contended that the contracts of assurance are primarily intended to benefit the facilities at which research takes place, rather than the vulnerable research subjects that the Common Rule is designed to protect. As the contracts of assurance consist mainly of a promise to abide by the requirements of the Common Rule--thus extending that promise to all research, irrespective of its funding source--they are, by definition, for the benefit of the research subjects.

One might, however, question what "benefit" a participant in a nontherapeutic study expects to derive from her participation. After all, there must be a benefit accruing to a third party in order for that third party to have standing to enforce the contract.
A research subject participating in a nontherapeutic trial, for example, does not expect to receive medical "treatment" in the traditional sense; she is presumably a healthy volunteer. Her participation is much more likely to benefit future generations than it is to have any medical benefit to her personally. Moreover, in many cases, an injured research subject may not realize she has been harmed until her participation has ended, arguably mooting a suit for "enforcement" of the agreement. What, then, is the "benefit" intended for the subject? Can she truly be a "beneficiary" of the contract?

The answer lies in the purpose of the contract of assurance. The contract of assurance does not speak to the potential therapeutic benefits of the research, or to the goals of the research; it is not a contract to perform research. Rather, the contract of assurance provides the terms by which research protocols must be approved and carried out, when and if the research institution conducts medical experimentation involving human subjects. Viewed this way, it seems clear that the research subjects are beneficiaries of the contract. The entire purpose of the contract is to guard participants' welfare. The benefit to a research subject in a nontherapeutic trial is that she is able to participate in a study that will benefit future generations, secure in the knowledge that she is protected from undue risk to her health and the integrity of her private information.

According to the Restatement's formulation, however, research subjects must also be "intended"--as distinguished from merely "incidental"--beneficiaries in order to have standing to sue for breach of contract. It is clear from the language of the Common Rule that human research subjects are intended beneficiaries to contracts of assurance. In sharp contrast to laws enacted for the protection of the general public, the Common Rule as codified expressly identifies the class of persons that DHHS sought to benefit. The regulations specifically set forth definitions of the persons who fall within the protected category of "human subject." This definition is necessarily sharpened by limitations in the individual assurances between the funding department or agency and the research facility as to what the research will entail.

Moreover, the Common Rule is designed to ensure adequate protection of human research subjects, even at the potential expense of a "greater good" for society at large. This means that research subjects are a discrete and particular class of people, distinct from the population at large, whose interests are intentionally protected by the Common Rule and by the contracts of assurance executed pursuant to it. Courts should infer the requisite intent to grant enforcement rights in those jurisdictions that adhere to the Restatement's rigid test for third-party standing in the context of government contracts.

C. Advantages of the Third-Party Beneficiary Approach

Given the many possible avenues of recovery for human research subjects, one might question whether research-subject plaintiffs need an additional litigation strategy. Although plaintiffs have recourse to state tort law, they face significant obstacles to recovery. The third-party beneficiary contract approach, therefore, may have broad implications insofar as existing tort law in most jurisdictions is inadequate to redress the harm sustained by human subject plaintiffs.

It makes little sense, however, to recognize a contract remedy if injured research subjects can only seek enforcement of the FWA between the research institution and the sponsoring federal agency in the form of specific performance. Although Professor Farnsworth notes that a third-party beneficiary "ordinarily has no right to restitution from the promisor," he also points out that such a beneficiary "may have a right to restitution in the unusual situation in which the beneficiary has itself rendered a performance that is received by the promisor." I submit that an injured research subject is an example of just such an unusual third-party beneficiary, thus giving the injured subject an incredible amount of leverage vis-à-vis the research institution. That is, if the third-party beneficiary can threaten a successful action for rescission of the
entire contract as a result of material breach, research institutions will have a new powerful incentive to offer substantial settlements to injured subjects.

Conclusion
Some may protest that recognition of a third-party beneficiary enforcement right for injured research subjects would not alter the current state of affairs; after all, the most vulnerable research subjects are arguably those participating in privately sponsored research conducted at facilities that do not receive any federal funding and are, therefore, not bound by an assurance. Because federal oversight does not extend to all privately funded research, the government "cannot know how many Americans currently are subjects in experiments, cannot influence how they have been recruited, cannot ensure that research subjects know and understand the risks they are undertaking and cannot ascertain whether they have been harmed." [FN203] We should not lose sight of the fact that, particularly in the context of genetic technologies, lack of jurisdiction over privately funded research raises serious concerns that the current regulatory scheme for protecting human subjects of research cannot be relied upon as the primary mechanism for preventing unethical experimentation or the inappropriate release of subjects' private information. Providing subjects with an additional legal tool in cases in which federal funds are involved, however, is a step in the right direction.


[FN2] Id. at 717. The researchers involved were later criticized for using a consent form in which the experimental drug administered to subjects in the study was described as "medication." Id. The consent form also failed to disclose that the drug was "not approved by the Food and Drug Administration." Id.

[FN3] Id.

[FN4] Id. at 717-18.


[FN6] See infra Part I.A.


In addition to the Common Rule, there are federal regulations that apply to research involving specific segments of the population, such as women, racial groups, and ethnic groups. Selected Policies, supra note 5, at 33; see also, e.g., Investigational and New Drug Applications, 21 C.F.R. §§ 312, 314 (2002); Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, 45 C.F.R. §§ 46.201-207 (2002); Policy on the Inclusion of Women and Racial and Ethnic Minorities in Externally Awarded Research, 60 Fed. Reg. 47,947 (Sept. 15, 1995); Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14,508 (Mar. 28, 1994).

There are other federal policies that apply to research in particular settings. These include research conducted in prisons or in an international setting. Selected Policies, supra note 5, at 33; see also, e.g., Protection of Human Subjects, 22 C.F.R. § 225 (2002); Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, 45 C.F.R. §§ 46.301-306 (2002). Depending on the source of funding or the agency charged with oversight of the research, more than
one of these policies may apply to a given research project. Selected Policies, supra note 5, at 33-34.


[FN10]. Steinbrook, supra note 1, at 716.


[FN12]. Ruth Faden & Tom Beauchamp, Removing "Deficiencies" in Human Research, Balt. Sun, Mar. 5, 2000, at 3C.

[FN13]. See infra Part I.C.


[FN21]. Nuremberg Code, reprinted in Selected Policies, supra note 5, at 12-13. The Declaration of Helsinki addresses protections for research subjects in both the therapeutic (i.e., research that promises a potential benefit to the participant) and nontherapeutic (i.e., research promising no direct benefit to the participant) contexts. See generally Declaration of Helsinki, supra note 15.
These principles include the following:

4. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

5. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.


For example, in 1963, patients at the Jewish Chronic Disease Hospital were injected with live cancer cells without their consent. In that same year, patients at the Willowbrook School--a residential facility for mentally disabled children--were intentionally infected with hepatitis so that researchers could study the disease. Henry K. Beecher, Ethics and Clinical Research, 274 New Eng. J. Med. 1354, 1356-59 (1966).


See generally James H. Jones, Bad Blood: The Tuskegee Syphilis Experiment (1993); William J. Curran, The Tuskegee Syphilis Study, 289 New Eng. J. Med. 730 (1973); Charles R. McCarthy, The Evolving Story of Justice in Federal Research Policy, in Beyond Consent: Seeking Justice in Research 11, 21 (Jeffrey P. Kahn et al. eds., 1998) (“If there was one event which most triggered public concern with the issues of human experimentation, it would have to be the public disclosure in July 1972 of the Tuskegee Syphilis Study ....” (citation omitted)).


National Research Act § 202(a) (directing Commission to “conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects”).


Belmont Report, supra note 19.

Respect for persons incorporates two ethical conventions: that people should be treated as "autonomous agents"
capable of taking action based on their own deliberations, and that people with a diminished degree of autonomy are still entitled to protection. Id. pt. B.1.

[FN34]. The principle of beneficence encompasses an obligation by researchers to ensure that they do no harm and that they "maximize possible benefits and minimize possible harms." Id. pt. B.2.

[FN35]. The Report uses justice to mean "fairness in distribution" (i.e., researchers must strive to ensure that all people are treated equally). No person should be denied a benefit without a good reason, or have an undue burden imposed upon him or her. Id. pt. B.3.

[FN36]. Id. pt. C.1.

[FN37]. Id. pt. B.1.

[FN38]. Id. pt. C.1.

[FN39]. Assessment of risks and benefits can be difficult, however, as "[o]nly on rare occasions will quantitative techniques be available for the scrutiny of research protocols." Id. pt. C.2.

[FN40]. Id. pt. C.3.

[FN41]. Id.

[FN42]. The current version of the DHHS regulations is codified at 45 C.F.R. § 46 (2002). In 1981, the DHHS regulations were revised to take account of the Report's recommendations. See IRB Guidebook, supra note 5, at Introduction pt. A. In 1983, the Commission added subpart D to provide additional protections for children participating in research. Id. pt. D. In 1991, the DHHS regulations were adopted by sixteen federal agencies and became the Federal Policy for the Protection of Human Subjects, or the Common Rule. Id.

[FN43]. Each department adopted the Common Rule separately; thus, it appears myriad times in the Code of Federal Regulations. See 56 Fed. Reg. 28,001, 28,002-32 (June 18, 1991) for a full list of the applicable regulations; see also Thomas John Babbo, Begging the Question: Fetal Tissue Research, the Protection of Human Subjects, and the Banality of Evil, 3 DePaul J. Health Care L. 383, 396 (2000) (stating that sixteen agencies incorporated the regulations into their own codes).

[FN44]. Notably, the Food and Drug Administration (FDA) declined to adopt the Common Rule as formulated by DHHS. It has, however, enacted a similar set of regulations. See 21 C.F.R. § 50 (2002). The few substantive differences between the Common Rule and the FDA regulations are irrelevant for the purposes of this Note.

[FN45]. Formerly the OPRR. See supra note 29 and accompanying text.

[FN46]. The Secretary of DHHS must ensure the establishment of Institutional Review Boards to oversee all biomedical or behavioral research involving human subjects. See 42 U.S.C. § 289(b)(2) (2000) (directing Secretary to establish processes for investigators to promptly report "incidences of violations of the rights of human subjects of research for which [federal] funds have been made available").

The assurance is a compliance agreement by an institution engaged in research conducted or supported by any federal department or agency that the institution will protect the rights and welfare of its research subjects. These assurances provide a mechanism to require researchers to protect the rights of human subjects embodied in the Belmont Report. Compare id. § 46.103(b)(1) (requiring "a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research"), with Protection of Human Subjects: Notice of Report for Public Comment, 44 Fed. Reg. 23,192, 23,194-97 (Apr. 18, 1979) (explaining need for informed consent, assessment of risks and benefits, and rules for the selection of subjects).


See 45 C.F.R. § 46.103(a).

Since the portions of an assurance relevant to this Note are the same in all four types of assurances, this Note uses the generic term "assurance" to mean any or all of the types of assurances discussed supra notes 48-51 and accompanying text.

See 45 C.F.R. § 46.103 (describing the minimum requirements for what must be included in these assurances).

Id. § 46.103(b)(1) (emphasis added).

Id.; see also U.S. Dep't of Health & Human Servs., Federalwide Assurance (FWA) for the Protection of Human Subjects for Domestic (U.S.) Institutions, at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasur.htm (last visited Mar. 4, 2003) (on file with the Columbia Law Review) (noting in the "Statement of Principles" section that another document containing guiding principles might be acceptable in lieu of the Belmont Report). Many universities, however, have decided to simply hold all research to the standards set forth in the DHHS regulations. Richard S. Saver, Critical Care Research and Informed Consent, 75 N.C. L. Rev. 205, 216 (1996); see also, e.g., Univ. of N.C. at Chapel Hill, Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects 1 (1995), available at http://www.med.unc.edu/irb/assur.html (on file with the Columbia Law Review) ("This institution is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the ... Belmont report, regardless of whether the research is subject to Federal regulation or with whom conducted or source of support.").


Id. § 46.103(b)(2).

Id. § 46.103(b)(3).
[FN59]. Id. § 46.103(b)(4)-(5).

[FN60]. Id. § 46.111.

[FN61]. See id.

[FN62]. See id. § 46.108 (setting forth functions of the IRB); id. § 46.109 (outlining specific responsibilities of IRB); id. § 46.111 (setting forth criteria for IRB approval of research); id. § 46.113 (providing for suspension or termination of IRB approval as a result of unfavorable review of implementation of protocol); id. § 46.115 (setting forth requirements for IRB record keeping, including records of continual review).

[FN63]. Id. § 46.109.

[FN64]. For a full description of the requirements of valid informed consent, see id. § 46.116.

[FN65]. Id. § 46.116(a)(1)-(3). See generally id. §§ 46.116-.117 (setting forth general requirements of informed consent and its documentation).

[FN66]. See, e.g., Jeffrey P. Kahn & Anna C. Mastroianni, Commentary, Moving from Compliance to Conscience: Why We Can and Should Improve on the Ethics of Clinical Research, 161 Archives Internal Med. 925, 925 (2001) [hereinafter Compliance to Conscience] (“The recent surge in federal oversight activity in research on human subjects has been a stimulus for renewed attention to ethics in research, and heightened public awareness of research issues means that the system of research must be above reproach.”).

[FN67]. Although the news stories written immediately after Jesse Gelsinger's death portrayed the experiment as a noble endeavor with a tragic outcome, that tone was soon replaced with one of anger and general distrust of the medical research community, as evidence of apparent financial conflicts of interest and breaches of protocol eventually emerged. See, e.g., Sheryl Gay Stolberg, The Biotech Death of Jesse Gelsinger, N.Y. Times, Nov. 28, 1999, § 6 (Magazine), at 138 (discussing media reports questioning researchers' failure to report deaths during previous gene therapy trials); Sheryl Gay Stolberg, Institute Restricted After Gene Therapy Death, N.Y. Times, May 25, 2000, at A20 (noting possible conflict of interest between research director and biotechnology company that funded studies and citing independent expert report claiming that research institute lacked knowledge and financial resources necessary to achieve compliance with federal regulations); Sheryl Gay Stolberg, Scientists Defend Suspended Gene Therapy, N.Y. Times, Feb. 15, 2000, at A20 (discussing failures in trial protocol, including failure to adequately document explanations of therapy's risks and potential benefits, failure to submit enrollment forms until after Gelsinger's death, and delay in notifying FDA about side effects experienced by other test subjects). For more on Jesse's death, see infra Part I.C.3.a; see also Complaint, Gelsinger v. Trs. of the Univ. of Pa., (Phila. County Ct. C.P. 2000), available at http:// www.sskrplaw.com/links/healthcare2.html (on file with the Columbia Law Review) [hereinafter Gelsinger Complaint].

[FN68]. See, e.g., Joseph B. Martin & Dennis L. Kasper, In Whose Best Interest? Breaching the Academic-Industrial Wall, 343 New Eng. J. Med. 1646, 1646 (2000) (“Over the past year, medical research involving human subjects has come under intense scrutiny. The issues of concern include the adequacy of informed consent, the surveillance of research protocols by institutional review boards, the reporting of adverse events, and investigators' conflicts of interest.”).

An "adverse event" refers to an instance of an unforeseen or unexpected negative reaction (including death) to the experimental treatment, therapy, or drug.

Although IRB members are supposedly foreclosed from participating in review of any project or study in which they have a conflicting interest, 45 C.F.R. § 46.107(d)-(e) (2002), there is no way to ensure that the research facility or individual researchers are not operating under such conflicts (or, for that matter, to ensure that IRB members are forthcoming in disclosing their conflicts and potential conflicts). See Robert Lee Hotz, Medical Tests Are Skewed, Study Finds, L.A. Times, Jan. 22, 2003, at 14 (citing Yale University study finding that "one-quarter of the biomedical researchers at universities had commercial ties serious enough to raise questions of financial conflict"). See generally Compliance Oversight Branch, Office for Human Research Protections (OHRP), OHRP Compliance Activities: Common Findings and Guidance 1- 3 (2002), available at http://ohrp.osophs.dhhs.gov/references/findings.pdf (on file with the Columbia Law Review) [hereinafter Common Findings] (detailing most common errors committed under the IRB system, including conflicts of interest and inadequate disclosure).


See Common Findings, supra note 71, pt. E.

Angell, Editorial Responsibility, supra note 72, at 278.

See, e.g., Compliance to Conscience, supra note 66, at 925 ("New technologies (gene therapy, stem cell transplants, and bioartificial organs, to name a few) raise new ethical issues. ... This is a time not only of great opportunity and promise for the pursuit of biomedical research, but also of great responsibility.").

Since many protocols are privately funded, there is no reliable way to determine the total number of human subject research protocols that are ongoing at any given time. From the statistics that are available, however, it is easy to see that the number of protocols (and the number of human subjects involved in those protocols) is quite large. For example, in 2000, the Department of Energy--one of sixteen federal agencies covered by the Common Rule--funded three hundred human subject research protocols, which involved a total of 1,420,988 human subjects. Dep't of Energy, Statistical Information on the 2000 Human Subjects Database, available at http:// www.eml.doe.gov/hsrd/hsr00/stats.cfm (last visited Mar. 23, 2003) (on file with the Columbia Law Review).


Donald F. Phillips, IRBs Search for Answers and Support During a Time of Institutional Change, 283 JAMA 729, 730 (2000) (citing shift from individual research projects to multiparty research as reason to update IRB system).

Id.; see also Human Subject Hearing, supra note 77, at 11 (remarks by George Grob) (noting shift to multi-site research, sometimes involving "hundreds of investigators" and "thousands of subjects").

Id. 

See supra notes 66-71 and accompanying text. For more on the role of IRBs, see supra notes 56-63 and accompanying text. 

For example, following the recent death of Ellen Roche (see supra notes 1-4 and accompanying text), Johns Hopkins University School of Medicine doubled the amount it allocated to IRBs from one million dollars per year to two million dollars per year. Steinbrook, supra note 1, at 719-20. 


Id. 

Id. 

Id. Compliance to Conscience, supra note 66, at 927. The Maryland Court of Appeals recently defined nontherapeutic research as "any manipulation, observation, or other study of a human being--or of anything related to that human being that might subsequently result in manipulation of that human being--done with the intent of developing new knowledge and which differs in any form from customary medical practice." Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 837 (Md. 2001). 


See IRB Guidebook, supra note 5, at Introduction pt. A. 

See, e.g., Compliance to Conscience, supra note 66, at 927 (noting this shift in focus toward access and arguing that it "must be balanced with ongoing vigilance concerning the protection of subjects"). As one commentator writes: Patients with life-threatening, devastating diseases, perhaps most notably cancer and acquired immune deficiency syndrome (AIDS), clamor for access to clinical trials. Federal policies governing research in the United States that once emphasized protecting subjects from dangerous research through such measures as informed consent and an assessment of risks and benefits of this research by institutional review boards (IRBs) now also promote access to clinical research. New requirements in these policies emphasize issues of selection of subject populations and the equitable distribution of the benefits and burdens of research participation across society. Jeffrey P. Kahn et al., Changing Claims About Justice in Research: An Introduction and Overview, in Beyond Consent, supra note 28, at 1 (citing NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14,508 (Mar. 28, 1994)) (other internal citations omitted). 

Kahn et al., supra note 91, at 1-2. 

Id. at 3. 

15,456-60 (proposed Mar. 31, 2003) (soliciting public comment on draft document outlining potential sources of conflict of interest in research setting and possible approaches for dealing with issues of financial conflict when they arise).

[FN95]. See Woodward, supra note 16, at 1951 (quoting a National Bioethics Advisory Council finding that lack of federal control over privately funded medical research limits ability to ensure that research subjects are treated properly).


[FN97]. See id. at 1516. Angell writes:

Academic medical institutions are ... growing increasingly beholden to industry. ... Some academic institutions have entered into partnerships with drug companies to set up research centers and teaching programs in which students and faculty members essentially carry out industry research. Both sides see great benefit in this arrangement. For financially struggling medical centers, it means cash. For the companies that make the drugs and devices, it means access to research talent, as well as affiliation with a prestigious "brand." The time-honored custom of drug companies' gaining entry into teaching hospitals by bestowing small gifts on house officers has reached new levels of munificence. Trainees now receive free meals and other substantial favors ... virtually daily, and they are often invited to opulent dinners and other quasi-social events. ... All of this is done with the acquiescence of the teaching hospitals.

Id.; see also Shalala, supra note 69, at 810 (advocating "a critical look at the mechanisms for the oversight of clinical trials, partnerships with the private sector, and ethical guidelines at each institution").


[FN99]. From 1980 to 2000, "commercial funding grew to 62% of all U.S. spending on biomedical research." Hotz, supra note 71, at 14. For example, Pfizer "spent $5.3 billion on research and development [in 2001], more than the National Science Foundation." Id.

[FN100]. Shalala, supra note 69, at 808; see also Pressures in Industry-Sponsored Research, supra note 98, at 8.

[FN101]. Shalala, supra note 69, at 810.


[FN103]. Shalala, supra note 69, at 809. In 1999-2001, for example, federally supported research was suspended at the following institutions: Duke University Medical Center (in 1999); University of Illinois, Chicago (in 1999); Virginia Commonwealth University (in 2000); University of Oklahoma Health Services Center (in 2001); and Johns Hopkins Medical Institutions (in 2001). Steinbrook, supra note 1, at 1.


Anderlik & Elster, supra note 29, at 220.

Id.; see also Gelsinger Complaint, supra note 67, PP 2, 57.

Id. PP 66-82.

Id. P 5.


E.g., Teen's Father: Gene Therapy's Risks Hidden, Chi. Sun-Times, Feb. 3, 2000, at 23 ("[I]t looked safe. It was presented as being safe. ... I was misled." (quoting Jesse's father)); Sheryl Gay Stolberg, Gene Patients Not Told All Facts, Researchers Ignore Rules, FDA Says, Times-Picayune (New Orleans), Jan. 27, 2000, at A1 [hereinafter Stolberg, Gene Patients] (explaining that Jesse and his father were "unaware" of the dangers involved).


Weiss & Nelson, Penn Settles Suit, supra note 110.

See, e.g., Roger L. Jansson, Note and Comment, Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions, 78 Wash. L. Rev. 229, 232 (2003) (noting that the federal regulations do not expressly provide a private right of action). As to whether there is an implied private right of action under the statutory scheme, see Whitlock v. Duke Univ., 637 F. Supp. 1463, 1475 (M.D.N.C. 1986), aff'd, 829 F.2d 1340 (4th Cir. 1987) (declining to reach the question of "whether a private cause of action in favor of an experimental subject arises from 45 C.F.R. § 46.109 and § 46.103(c)"). The court held, however, that these regulations established the standard of care to be applied in assessing the plaintiff's common law claims. Id. at 1471. Because the defendant did not violate this standard of care, the court held that it would not be liable even if there were a private cause of action under the regulations. Id. at 1475.

See President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavior Research, Compensating for Research Injuries 82-97 (1982) (describing traditional remedies such as negligence and strict liability); Jansson, supra note 114, at 233-38 (discussing the courts' nascent framework for analyzing negligence actions in the research context); Comment, The Legal Implications of Psychological Research with Human Subjects, 1960 Duke L.J. 265, 272 [hereinafter Legal Implications] (discussing the availability of affirmative defenses, such as assumption of risk, to researchers sued by participants).

Ultimately, the sponsoring university would probably be vicariously liable in suits against researchers. See Restatement (Second) of Agency § 243 (1958). It is unclear whether IRB members could be held liable in negligence action brought by research subjects. See Jansson, supra note 114, at 238 (noting the "split in authority [as to] whether state peer review statutes" shield IRB members from liability). In at least one state, IRB members enjoy immunity from civil liability. See Va. Code Ann. §8.01-44.1 (Michie 2001). In addition, many university policies expressly provide that the university will indemnify individual IRB members; were this not the case, people would likely be reluctant to serve on IRBs. John A. Robertson, The Law of Institutional Review Boards, 26 UCLA L. Rev. 484, 535 (1979).

See infra notes 121-127 and accompanying text for a discussion of the only case that has expressly held that the
Common Rule establishes a duty and standard of care that may be used in negligence actions.


[FN118] Such grounds include general negligence, strict product liability, failure to warn, negligent infliction of emotional distress, malpractice, and negligent misrepresentation. For a detailed discussion of duty and standard of care in potential negligence actions against researchers, see generally Jansson, supra note 114 (arguing that research-subject plaintiffs should be able to prevail in negligence actions against researchers, because the researcher-subject relationship imposes a special duty on the researcher, and the Common Rule as codified in the federal regulations should serve as the minimum standard of care).


[FN120] Id. § 36, at 220-33.

[FN121] 782 A.2d 807, 811-12 (Md. 2001). In Whitlock v. Duke Univ., 637 F. Supp. 1463 (M.D.N.C. 1986), aff’d, 829 F.2d 1340 (4th Cir. 1987), the Middle District of North Carolina found that the Common Rule was the appropriate standard of care in negligence actions involving defective consent in the research context; it did not, however, reach the question of whether the Common Rule imposes a duty, because it found that the standard of care had not been breached. Id. at 1475.


[FN123] Id. at 821 ("The project required that small children be present in the houses. To facilitate that purpose, the landlords ... were encouraged, if not required, to rent the properties to tenants who had young children.").

[FN124] Id. at 818-20.

[FN125] Id. at 849.

[FN126] Id. at 858.

[FN127] Id. at 835-36 (holding that "the very nature of nontherapeutic scientific research on human subjects can, and normally will, create special relationships out of which duties arise").

[FN128] The violation of a safety statute is often considered conclusive proof of the first two elements of a negligence action. Prosser & Keeton, supra note 119, § 36, at 223-24 (discussing negligence per se).

[FN129] See, e.g., Grimes, 782 A.2d at 818 ("It may well be that ... the trial courts will determine that no damages have been incurred in the instant cases and thus the actions will fail for that reason.").


[FN131] IRB members' liability would have to be independently established; presumably, members of the IRB would not be vicariously liable for the torts of a researcher whose protocol they had approved, since there is no agent-principal relationship between IRBs and researchers. Furthermore, IRB members may be shielded from liability for negligence. See supra note 115 and accompanying text.

[FN132] See Prosser & Keeton, supra note 119, § 30, at 164 (discussing application of the reasonable person standard).
Negligent treatment or delay of treatment that decreases a patient's likelihood of survival may be sufficient to prove proximate cause under the doctrine commonly referred to as "loss of chance." See generally Robert S. Bruer, *Loss of Chance as a Cause of Action in Medical Malpractice Cases: Wollen v. DePaul Health Center*, 59 Mo. L. Rev. 969 (1994) (discussing loss of chance theory in medical malpractice cases and noting the poor fit between the loss of chance theory and traditional analysis of causation). Although some states recognize the "loss of chance" doctrine, many jurisdictions have either expressly rejected it or have otherwise refused to adopt it. Id.


*Bonner*, 126 F.2d 121 (D.C. Cir. 1941).

*Id.* at 121-22.

*T.D. v. N.Y. State Office of Mental Health*, 650 N.Y.S.2d 173, 185 (1996) (contrasting research, which "offers no benefit or only minimal benefit to the subject," with "treatment where the sole motivation is a beneficial therapeutic effect on the patient with minimal adverse side effects").

*Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 855 (Md. 2001) (holding that "in nontherapeutic research using children ... the consent of a parent alone cannot make appropriate that which is innately inappropriate").

See Richard S. Saver, *Critical Care Research and Informed Consent*, 75 N.C. L. Rev. 205, 226 (1996) (noting that "damages are a required element [of negligence], which may be difficult to prove in the absence of physical harm"). The old common law rule that emotional distress was only compensable if accompanied by contemporaneous physical injury has now been abrogated in many jurisdictions. See, e.g., *Thing v. la Chusa*, 48 Cal. 3d 644, 667-68 (1989) (concluding that a plaintiff who does not suffer physical injury may recover for negligent infliction of emotional distress in some circumstances, but finding that plaintiff could not recover in the case at bar, because she was not present at the scene of the event that caused her emotional injury); *Bowen v. Lumbermens Mut. Cas. Co.*, 517 N.W.2d 432, 442-43 (Wis. 1994) (holding that plaintiff could prevail in suit for negligent infliction of emotional distress without proving physical manifestation of severe emotional distress); see also Prosser & Keeton, supra note 119, at 56-57 (noting that "[i]t has gradually become recognized that ... the infliction of mental injury may be a cause of action in itself").

See Legal Implications, supra note 115, at 271-73.

See generally William L. Prosser, *Privacy*, 48 Cal. L. Rev. 383, 389-407 (1960) (laying out four theories on which action for invasion of privacy may be brought, including public disclosure of private facts); Prosser & Keeton, supra note 119, §§ 111-117, at 771-869 (discussing defamation and privacy); see also, e.g., *Alberts v. Devine*, 479 N.E.2d 113, 116 (Mass. 1985) (recounting minister's claim that his psychiatrist breached duty of confidentiality by disclosing minister's "'diagnosis, condition, behavior, or treatment'" to church superiors); *Bratt v. Int'l Bus. Machs.*, 467 N.E.2d 126, 130 (Mass. 1984) (summarizing plaintiff's allegations of libel and breach of right to privacy after office memorandum discussing his mental condition was circulated).

See, e.g., *City of Inglewood v. City of Los Angeles*, 451 F.2d 948, 956 (9th Cir. 1972) (holding that administrative remedies must be exhausted before judicial remedies can be pursued).
See Robert S. Adelson, Note, Third Party Beneficiary and Implied Right of Action Analysis: The Fiction of One Governmental Intent, 94 Yale L.J. 875, 875 (1985). The most frequent objection to recognizing such rights is that they encroach upon the doctrine of separation of powers: "Because Congress at times provides explicitly for private causes of action," its failure to do so may reflect a purposeful choice that should not be disturbed by judicial lawmaking. Id. at 892; see also John Arthur Laufer, Note, Alexander v. Sandoval and Its Implications for Disparate Impact Regimes, 102 Colum. L. Rev. 1613, 1619 (2002) (arguing that "legislative intent--as revealed by statutory language and structure--is the sole touchstone in the implied right of action inquiry").

This approach would not raise the same separation of powers concerns raised by implied rights of action. Adelson, supra note 144, at 892-93 ("[A]lthough judicial implication of private rights potentially conflicts with ... separation-of-powers, .... judicial recognition of ... third party beneficiary standing may reinforce the principles of separation of powers .... Because [it] requires analysis of congressional and agency intent ... it honors rather than usurps the decisionmaking powers of the legislative and executive branches.").

Arthur R. Block, Enforcement of Title VI Compliance Agreements by Third Party Beneficiaries, 18 Harv. C.R.-C.L. L. Rev. 1, 23 (1983).

See, e.g., Adelson, supra note 144, at 889-90 (citing Perry v. Hous. Auth., 664 F.2d 1210, 1218 (4th Cir. 1981), which held, with little discussion, that plaintiffs are not third-party beneficiaries, based on the absence of a private right of action in the statute).

Adelson, supra note 144, at 875; see also E. Allan Farnsworth, Contracts § 10.6, at 691 (3d ed. 1999).


Restatement (Second) of Contracts § 308 (1979) [hereinafter Restatement]; Block, supra note 146, at 18-19.

Block, supra note 146, at 18.

Farnsworth, supra note 148, § 10.3, at 679 (noting that, as to courts' analyses of third-party beneficiary status, the Restatement (Second) has had "substantial influence ... in many jurisdictions").

Restatement, supra note 150, § 302.

Id.; Block, supra note 146, at 18.

Restatement, supra note 150, § 302(1).

Farnsworth, supra note 148, § 10.3, at 679.

Block, supra note 146, at 20.

See Farnsworth, supra note 148, § 10.3, at 679.

Id. § 10.6, at 689-91.

Id.; see supra notes 152-158 and accompanying text.
[FN161]. See id. (discussing special problems posed by government contracts and the Restatement's attempt to address them with a more stringent test for third-party beneficiary status).

[FN162]. Adelson, supra note 144, at 878-79.

[FN163]. See Restatement, supra note 150, § 313(1) (applying the general third-party standing rules to government contracts, "except to the extent that application would contravene the policy of the law authorizing the contract or prescribing remedies for its breach").

[FN164]. Section 313(2) reads:
[A] promisor who contracts with a government or governmental agency to do an act for or render a service to the public is not subject to contractual liability to a member of the public for consequential damages resulting from performance or failure to perform unless
(a) the terms of the promise provide for such liability; or
(b) the promisee is subject to liability to the member of the public for the damages and a direct action against the promisor is consistent with the terms of the contract and with the policy of the law authorizing the contract and prescribing remedies for its breach.
Id. § 313(2).

[FN165]. As adopted by the Restatement. Id. § 313(1).

[FN166]. See id. § 313(2).

[FN167]. See, e.g., Holbrook v. Pitt, 643 F.2d 1261, 1270 n.17 (7th Cir. 1981) (expressing approval of intent-to-benefit test); Norfolk & Western Co. v. United States, 641 F.2d 1201, 1208-09 (6th Cir. 1980) (same); DFP Mfg. Corp. v. Northrop Grumman Corp., 1999 WL 33458384, at *7 (E.D.N.Y., Mar. 23, 1999) (noting that, under New York law, a putative third-party beneficiary may recover for breach of contract "only by establishing (1) the existence of a valid ... contract between other parties, (2) that the contract was intended for his benefit and (3) that the benefit to him is sufficiently immediate ... to indicate the assumption by the contractive parties of a duty to compensate him if the benefit is lost." (quoting Burns Jackson Miller Summit & Spitzer v. Lindner, 464 N.Y.S.2d 712, 722 (N.Y. 1983))); Taylor Woodrow Blitman Constr. Corp. v. Southfield Gardens Co., 534 F. Supp. 340, 343 (D. Mass. 1982) (considering both intent to benefit and reasonableness of reliance in its third-party beneficiary analysis). But see, e.g., Price v. Pierce, 823 F.2d 1114, 1121 (7th Cir. 1987) (holding that the test for determining whether prospective tenants of subsidized housing were third-party beneficiaries of contracts between state housing authority and developers of low-income housing was whether contracting parties intended prospective tenants to have right to sue in event of a breach); Hodgdon v. United States, 919 F. Supp. 37, 40 (D. Me. 1996) (holding that "the contract must reflect the intent not merely to benefit the third-party but also to give him the direct right to compensation or to enforce that right against the promisor" (citing Baudier Marine Elecs. v. United States, 6 Cl. Ct. 246, 249 (1984), aff'd, 765 F.2d 163 (Fed. Cir. 1985); German Alliance Ins. Co. v. Home Water Supply Co., 226 U.S. 220, 230 (1912)).

[FN168]. See, e.g., Nguyen v. United States Catholic Conference, 719 F.2d 52, 55-56 (3d Cir. 1983) (refusing to subject promisor to duty unless intention is manifested in contract); McCullough v. Redevelopment Auth., 522 F.2d 858, 867-68 & n.27 (3d Cir. 1975) (rejecting argument that provisions are mandatory, and upholding position that--if binding at all--they are binding only as implied obligation); Carson v. Pierce, 546 F. Supp. 80, 87 (E.D. Mo. 1982) (holding that statute's "provision ... was not intended to create a statutory right or a private cause of action").


[FN171]. Farnsworth, supra note 148, § 10.3, at 684.


[FN173]. See id.; Block, supra note 146, at 12.

[FN174]. Waters, supra note 172, at 1176. "Any contract in excess of $2,500 entered into by any Federal department or agency ... shall contain a provision requiring that ... the party contracting with the United States shall take affirmative action to employ and advance in employment qualified handicapped individuals ...." Id. at 1176 n.310 (quoting The Rehabilitation Act of 1973 § 503, 29 U.S.C. § 793 (1982)). See also, e.g., Howard v. Uniroyal, Inc., 719 F.2d 1552, 1555 (11th Cir. 1983) (holding that section 503 "preempts a qualified individual's claim under state law as a third party beneficiary of the affirmative action clause"); Davis v. United Air Lines, 662 F.2d 120, 120 (2d Cir. 1981) (finding that employee did not have a private right of action against employer under section 503); Simpson v. Reynolds Metals Co., 629 F.2d 1226, 1244 (7th Cir. 1980) (holding that section 503 "does not authorize by implication a private right of action"); Rogers v. Frito-Lay, Inc., 611 F.2d 1074, 1079-85 (5th Cir. 1980) (same holding); Hoopes v. Equifax, Inc., 611 F.2d 134, 135 (6th Cir. 1979) (same).

[FN175]. See, e.g., Waters, supra note 172, at 1186-88 (discussing Fuzie v. Manor Care, Inc., 461 F. Supp. 689, 690 (N.D. Ohio 1977), which held that there was no implied private remedy under the Medicaid Act because, inter alia, plaintiff had an adequate remedy under state law as third-party beneficiary of the provider's agreement between nursing home operator and the State of Ohio).

[FN176]. See, e.g., Bossier Parish Sch. Bd. v. Lemon, 370 F.2d 847, 850 (5th Cir. 1967) (upholding "an injunction ordering the school authorities to submit a desegregation plan for Bossier public schools").


[FN178]. 370 F.2d at 850.

[FN179]. Id.

[FN180]. Block, supra note 146, at 34-35.

[FN181]. Farnsworth, supra note 148, § 10.6, at 690-91.

[FN182]. Id.

[FN183]. E.g., Taylor Woodrow Blitman Constr. Corp. v. Southfield Gardens Co., 534 F. Supp. 340, 343 (D. Mass. 1982) (stating that particular claims before the court were not meritorious, but "[i]t is well established under federal common law that one who is not a party to a contract may nevertheless have enforceable claims under the contract if the contract was made for his direct benefit"). The Third Circuit, however, has consistently disfavored third-party claimants. See, e.g., McCullough v. Redevelopment Auth., 522 F.2d 858, 867-68 n.27 (3d Cir. 1975); NAACP v. Wilmington Med. Ctr., 453 F. Supp. 280 (D.

[FN184] Block, supra note 146, at 26. Courts have rejected such claims on other grounds as well. For instance, some have held that, "while there was an intention to benefit a class, the plaintiff d[id] not fall within that class." Id. at 26-27 (citing Matthew v. United States, 471 F. Supp. 937, 940 (S.D.N.Y. 1979), which held that no agreement had been breached by the contracting parties). Other courts have found that "state statutes preclude third party recovery on certain contracts." Id. at 27 (citing Pankow Constr. Co. v. Advance Mortgage [sic] Corp., 618 F.2d 611, 612 (9th Cir. 1980) (preventing contractor from collecting balances due on Department of Housing and Urban Development insured development)). Some have held that although a plaintiff might have a claim as a third-party beneficiary, he must exhaust other remedies before he can recover on it. Id. (citing City of Inglewood v. City of Los Angeles, 451 F.2d 948, 956 (9th Cir. 1972)).

[FN185] For years, courts have applied the third-party beneficiary doctrine to other "public law" contracts. For example, courts have recognized that the beneficiaries of Title VI contracts of assurance, in which recipients of federal funds agree, as a condition to disbursement of those funds, to abide by the nondiscrimination requirements of Title VI of the Civil Rights Act of 1964. See supra Part III.B.

[FN186] See supra Part I.


[FN188] 45 C.F.R. § 46.103(a)-(b).

[FN189] Id. § 46.122 ("Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.")

[FN190] See, e.g., T.D. v. N.Y. State Office of Mental Health, 650 N.Y.S.2d 173, 188-89 (1996) (noting that the specific provisions of the MPA in question "allowed OMH and the Foundation to exempt themselves from certain federal reporting requirements"). Among the reporting requirements of the Common Rule from which OMH exempted itself was that specified in 28 C.F.R. § 46.103(b)(5) (2002). That section provides for "prompt reporting to the IRB, appropriate institutional officials," and the appropriate federal department or agency head of any unanticipated problems involving risks to subjects or others, among other things. The court went on to note that in lieu of this provision, "defendants obligated themselves to an 'alternative reporting requirement' for non-Federally funded research, which requires that the information, which would have been reported to DHHS, be reported to the Foundation." T.D., 650 N.Y.S.2d at 189.

[FN191] Section 46.123 provides:
The department or agency head may require that ... support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy. In making decisions about supporting or approving ... proposals ... the department or agency head may take into account ... whether the applicant or the person or persons who would direct or has directed the scientific and technical aspects of an activity have ... materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

45 C.F.R. § 46.123(a)-(b).

[FN192] See supra Part IV.A.
[FN193] Recall that only intended beneficiaries can recover as third-party beneficiaries. See supra Part III.A.

[FN194] See supra Part III.A.

[FN195] See supra Part III.A.

[FN196] See 45 C.F.R. § 46.102(f) (defining "human subject"); id. § 46.101 (defining scope of research covered by the Common Rule).


[FN198] See supra notes 159-171 and accompanying text; Restatement, supra note 150, § 313(1)-(2).

[FN199] See supra Part II.

[FN200] See supra Part II.


[FN202] Id. § 10.7, at 692 n.3 (citing Restatement (First) of Contracts § 356).

[FN203] Letter from Harold T. Shapiro, Chair, National Bioethics Advisory Commission, to William Jefferson Clinton, President of the United States (May 4, 1999) (on file with the Columbia Law Review); see also Human Subject Hearing, supra note 77, at 124 (prepared statement of Robert Amdur, M.D., Associate Chair, Clinical Affairs, Dep't of Radiology and Oncology, Univ. of Fla.) (“To permit private funders of research to proceed without the same ethical imperatives and other safeguards required for federally funded studies is unsupportable, and we hope, soon to be an anachronism.”).