TWO MODELS OF INFORMED CONSENT

By Lynn A. Jansen*

Abstract: *Informed consent is a central concept in the literature on the ethics of clinical care and human subjects research. There is a broad consensus that ethical practice in these domains requires the informed consent of patients and subjects. The requirements of informed consent in these domains, however, are matters of considerable controversy. Some argue that the requirements of informed consent have been inflated, others that they have not been taken seriously enough. This essay argues that both sides are partly right. To advance this argument, the essay distinguishes a general doctrine of informed consent from what it characterizes as "models of informed consent." A general doctrine articulates a set of requirements for informed consent and then adjusts these requirements to fit the context in which they are to be applied. In contrast, different models of informed consent impose different requirements in different contexts. The essay contends that different models of informed consent are needed for clinical care and clinical research. It outlines these two models, articulates the rationale for distinguishing them, and considers and rebuts the objection that clinical care and clinical research are too deeply intertwined in contemporary medicine for the models approach to apply to them.*

KEY WORDS: informed consent, exploitation, therapeutic misconception, research ethics

Informed consent is a central concept in biomedical ethics. It was not always the case. Prior to the 1950s, there is little mention of this idea in the literature on the ethics of clinical care and human subjects research.[1] Discussion of informed consent in these domains has a fairly recent history. Nevertheless, this history has shaped how the concept has been understood and how it has been applied in practice. A dominant trend in the medical ethics literature has been to propose a general account of informed consent that is taken to apply to both clinical medicine and human subjects research. This essay resists that trend. Despite the current consensus that informed consent is necessary for ethical practice in biomedical domains, there is considerable underlying controversy over its requirements. Some writers think that the requirements of informed consent have been inflated, others think that they have not been taken seriously enough. In a sense, this essay argues that both sides are right. To advance this argument, I will distinguish a doctrine of informed consent from what I will term "models of informed consent"; and I will argue that models of informed consent impose different

* Center for the Philosophy of Freedom, University of Arizona, lynnjansen@email.arizona.edu. Competing Interests: The author declares none.

[1] Thomas Beauchamp, "Informed Consent: Its History, Meaning and Present Challenges," *Cambridge Quarterly of Healthcare Ethics* 20, no.14 (2011): 515–23.

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requirements. Further, I will argue that different models of informed consent are appropriate for different contexts. Of special interest in this essay is the difference in context between clinical care and clinical research.

Section I introduces some terminology that will be useful for the argument that follows. Sections II and III describe the difference between a doctrine and a model of informed consent. As I will explain, the requirements imposed by a model are determined by the normative functions of consent that are applicable to the context to which the model applies. These sections also offer a preliminary defense of the claim that different models of informed consent apply to clinical medicine and human subjects research. Section IV discusses an important complication that presents a challenge to the preliminary argument. The complication involves the possibility, and increasingly the reality, of blurred boundaries between medicine and research. Consideration of this complication leads me to propose, in Section V, a sharper formulation of the relevant divide between the two models of informed consent that I have proposed. Before concluding, the essay discusses the possibility of extending its main line of argument further by introducing additional distinctions between biomedical contexts that call for more fine-grained models of informed consent.

I. Background Issues

Informed consent to an action could be taken to occur when a person with an adequate understanding of the nature of the action mentally assents to it. I send a text to my friend, Lori, and ask her if she will house-sit my dog Brian for the weekend. Upon receiving the text, she assents to this request and forms the intention to do so. Has Lori consented to house-sit Brian? Perhaps in one sense yes; but not in the sense that is relevant here. For Lori to give informed consent to house-sit Brian, she must communicate her willingness to do so to me. Her communication is an act that is necessary in order for her mental assent to generate an obligation on her part to do so.

Informed consent, as it is commonly understood, changes the moral relations between the consenting partners. It transforms impermissible acts into permissible ones, as when I give you permission to read my mail, and it generates obligations, as when I promise to provide some service to you. Yet if informed consent is to be morally transformative, it must include a behavioral component. This much is common ground among writers on informed consent in bioethics.

It is less clear that an appropriate mental state also is required for informed consent to occur in this domain. Franklin Miller and Alan Wertheimer have proposed an interesting account of informed consent that shifts the focus from the mental states of the interacting partners to the circumstances under which they consent. As they see matters,

> The transformative power of B's consent (or behavior) is a function of the *circumstances* under which B chooses (including the behavior of A) rather than the specific mental states that characterize or motivate B's choice.[2]

On this picture of informed consent, the key consideration is the fairness of the circumstances that yield the moral transformation. When A and B interact, both have interests at stake, and the interests of both need to be given their due in determining what requirements of informed consent apply to their interaction.

Miller and Wertheimer present their account as a competitor to the standard view in bioethics that informed consent is a function of autonomous authorization. To appreciate the difference between the two accounts, it will help to consider a simple example.

> *Routine Procedure*: Ellen's physician recommends that she undergo surgery to correct damaged ligaments in her knee. The recommended surgery is the standard treatment for the kind of injury that she has. In line with legal requirements, Ellen's physician discloses relevant information concerning the surgery to her, but makes no effort to help her understand this information. Ellen signs a consent form without reading the information and her physician proceeds with the operation.

Autonomous authorization to a medical procedure requires at least that the patient understand the relevant information regarding the procedure and the risks that it presents. So, on the autonomous authorization account of informed consent, Ellen has not given informed consent to the procedure. But arguably her physician has treated her fairly in this example. He has given her a fair opportunity to understand the relevant information. If so, then, on the fair transaction account of informed consent, Ellen has consented to the procedure.

The disagreement between the two accounts of informed consent illustrated by this example turns on a disagreement over what Miller and Wertheimer call the "ontology" of consent. On the autonomous authorization account, informed consent requires the presence of an appropriate mental state. On the fair transaction account, a behavioral act—the signing of the relevant form—under fair circumstances can suffice for informed consent to occur.

Some might protest that informed consent is not possible without an appropriate mental state. Informed consent just means consent with comprehension of the relevant information. But if this objection were raised,

[2] Alan Wertheimer and Franklin Miller, "Preface to a Theory of Consent Transactions in Research: Beyond Valid Consent," in Alan Wertheimer, *Rethinking the Ethics of Clinical Research* (Oxford: Oxford University Press, 2011), 45–115 at 89 (italics in original).

then a proponent of the fair transaction account could grant the semantic point without much loss to her position. She could distinguish informed consent from morally transformative consent, and she could insist that the latter can occur in the absence of the former. She then could claim that the type of consent that matters, whatever it is called, does not require the presence of an appropriate mental state.[3]

There is, however, a different way to explain the disagreement between those who think that informed consent is given in *Routine Procedure* and those who think it is not. Ellen signed the form, and this was an intentional act. But for this intentional act to count as informed consent, certain background standards need to be satisfied. The signing of the form must be voluntary, for example. Disclosure of relevant information may be another necessary standard, and comprehension of that information yet another. The disagreement in this case, accordingly, may not be over the ontology of consent, but over the standards that apply to it. One party thinks that disclosure is enough, while the other thinks that both disclosure and comprehension are required.

Moreover, the standards themselves can be the source of disagreement. Each party to the dispute may agree that disclosure of relevant information is necessary for informed consent, but disagree over how much, or what kinds of, information must be disclosed.[4] Or, both parties might agree that comprehension is required, but have differing views as to what constitutes adequate comprehension. In this case, the disagreement is not over what standards apply to informed consent, but rather over the stringency of the standards that do apply.

Accounts of informed consent thus can differ along several different dimensions—ontology, standards, and stringency. In addition, it is often thought that, at least in some contexts, the validity of informed consent requires certain regulatory mechanisms to be in place. For example, the consent forms for research trials conducted in the United States that involve human subjects must be approved by special review boards—institutional review boards (IRBs). If these forms are not submitted for this approval, or if they are submitted but rejected, then the participants' consent is not morally transformative, and thus conducting the research is impermissible. The same regulations do not apply to standard medical care. The consensual nature of the physician/patient relationship is not overseen by outside panels. (To the extent that consent to medical care is regulated, it is regulated by law; but in practice there is very little oversight of the informed consent process in standard medical care.)

[3] Ibid. (Perhaps it would be more apt to say that Ellen in *Routine Procedure* has given *morally transformative* consent, but not *informed* consent, to the procedure. But I will continue to speak of informed consent to refer to both consent when one is actually informed and consent when one has been given a fair opportunity to be informed.)

[4] Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, 4th edition (New York: Oxford University Press, 1994), 146–57.

This points to a fourth dimension that an account of informed consent must address. It concerns the type of regulatory and enforcement mechanisms, if any, that are required for the kind of informed consent under consideration to be valid. Drawing on these four dimensions, I now want to explain how a model of informed consent differs from a doctrine of informed consent.

II. Models of Informed Consent

Writers in bioethics for the most part do not present informed consent as a basic or first principle. Candidates for first principles include autonomy, beneficence, and justice. Rather, informed consent is depicted as a derivation or application of these first principles. For example, the Belmont Report, which is a landmark text in the history of informed consent in biomedicine, articulates an account of informed consent for research on human subjects that is described as an application of the background principle of respect for persons.[5] The authors of the Report might have claimed that the account of informed consent that they were proposing was applicable only to practices involving research on human subjects. But they took themselves to be articulating the key elements of a general account of informed consent. The elements they highlighted were: disclosure of relevant information, comprehension of disclosed information, and voluntariness.[6]

Most discussions of informed consent since the publication of the Belmont Report have added capacity as a basic element of the concept. Informed consent requires that the person who is consenting have the capacity or competence to do so. Determination of capacity in patients and prospective research participants is not always easy or straightforward, but in theory the requirement is uncontroversial.[7]

The authors of the Belmont Report presented informed consent as an application of the more general ethical principle of respect for persons. In like fashion, Beauchamp and Childress in their standard textbook on medical ethics presented informed consent as an application of the principle of autonomy. They agreed that informed consent requires the four elements of capacity, disclosure, understanding, and voluntariness. I will refer to a general account of informed consent of the kind proposed by the authors

[5] The Belmont Report was written by a committee of experts selected by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. It was published in 1979.

[6] Belmont Report (1979).

[7] It might be claimed that capacity is not a distinct element of informed consent, but a presupposition of the understanding element. One can fail to understand while having capacity, but one cannot understand while lacking capacity. But decision-making capacity may require more than the capacity to understand relevant information that is disclosed in the informed consent process. For example, it may require that one be able to appreciate the information that is disclosed. See Paul Appelbaum, "Assessment of Patients' Competence to Consent to Treatment," *New England Journal of Medicine* 357, no.18 (2007): 1834–40.

of the Belmont Report or by Beauchamp and Childress as a *doctrine of informed consent*, since the account attempts to identify the conditions that must be satisfied for a purported consensual interaction to qualify as a genuine (that is, morally transformative) consensual interaction. The doctrine of informed consent tells professionals what needs to be done—such as disclose relevant risk/benefit information in a way that can be understood—to effect the relevant moral transformation between the rights and duties of the interacting parties.

The demands of a doctrine of informed consent depend obviously enough on the background principle from which it is derived. But regardless of its exact content, the doctrine will be general in two senses. First, it will identify a set of key elements, such as capacity, disclosure, understanding, and voluntariness, that must be satisfied for informed consent to occur. Second, it will apply to domains or contexts to which the background principle applies. For example, if informed consent is an application of the background principle of autonomy, then it should apply to contexts in which respect for autonomy is important. This plainly covers both medical and research domains.

These aspects of generality explain why it is common to view the doctrine of informed consent as applying to both clinical medicine and human subjects research. This might give one initial pause. Are there significant enough differences between these two contexts such that we should not expect there to be a unified doctrine of informed consent that applies to both of them? The proponent of such a unified doctrine can respond that the characterization of the basic elements of informed consent can be adjusted to fit the context to which it applies. The requirements of informed consent in the research context can be made more demanding than those in the medical context.[8] The requirements for disclosure in the research context may be more stringent than those in the context of clinical medicine, for example.

A doctrine of informed consent can be further adjusted to the contexts in which it applies by attending to the other dimensions of informed consent that I described in the previous section. The key elements of informed consent correspond to what I referred to as standards. The stringency of these standards and the regulatory mechanisms that enforce them also can be calibrated to fit the relevant contexts. However, there are limits to how much adjustment can occur on this approach. If someone were to argue that the principle of informed consent has four basic standards in clinical medicine, but six basic standards in clinical research, then she would be giving up on the idea that there is a general doctrine of informed consent that

[8] R. J. Levine, *Ethics and Regulation of Clinical Research* (New Haven, CT: Yale University Press, 1988).

applies to both domains. Here, talk of different models of informed consent would be more apt.[9]

Different statements of the doctrine of informed consent conflict with one another. Writers argue over which statement best characterizes the doctrine. But models of informed consent need not compete in this way. One model may be appropriate for one context, while a different model may be better suited for another context. Stepping back from biomedicine, and scanning the full range of contexts in which informed consent is important, this point looks especially compelling. Why expect that there is a general doctrine of informed consent that applies to contexts as diverse as commercial transactions, sexual relations, and clinical medicine? It might be thought that if the same background principle applies to these very different contexts, then a unified account is possible. But I will try to show that it is more plausible to construct different models of consent that apply to them.

Some people might grant the usefulness of the models approach in general, but insist that the specific contexts of medicine and research are sufficiently similar that the same model should apply to both of them. They might point to the fact that the two contexts overlap in various ways. Researchers are often physicians, and research subjects often join trials in the hopes of receiving innovative treatment. This overlap has generated ethical concern of its own. Studies have repeatedly found that research subjects frequently manifest a "therapeutic misconception." They confuse the experimental aims of clinical research with the therapeutic aims of clinical medicine.[10] More precisely, the therapeutic misconception involves at least one of the following two errors: (i) falsely believing that treatment received in a research trial will be individualized to a participant's own situation; and (ii) falsely believing that the primary purpose of research is to provide therapeutic benefits to its participants rather than to promote generalizable scientific knowledge.[11]

A brief consideration of why the therapeutic misconception has generated ethical concern about clinical research can help to bring out the important differences between the contexts of research and medicine and why the same model of informed consent may not be appropriate for both. The most fundamental difference is the difference in purpose in the two practices. The primary purpose of clinical medicine is to benefit the patient. In contrast, the primary purpose of research on human subjects is to generate scientific

[9] Looking over different models of informed consent, one might pick out the standards shared by all of them and then claim that the shared standards constitute the core of informed consent. This common core would be neither a doctrine of informed consent nor a model of informed consent and it would not provide an account of when informed consent is valid in any particular context.

[10] Paul Appelbaum and Charles Lidz, "The Therapeutic Misconception," in *The Oxford Textbook of Clinical Research Ethics*, ed. Ezekiel Emanuel, Christine Grady, Robert Crouch, et al. (New York: Oxford University Press, 2008), 633–44.

[11] Gail E. Henderson et al., "Clinical Trials and Medical Care: Defining the Therapeutic Misconception," *PLoS Med* 4, no. 11 (2007).

knowledge that may benefit future patients. Importantly, this means that clinical research is potentially exploitative in a way that clinical medicine is not.[12] When clinical medicine goes well, the patient's interests are not sacrificed to promote a social goal.[13] But when clinical research goes well the research subject's interests can be set back for the sake of medical progress. Indeed, as I have argued elsewhere, some research trials can be described as "bad deal trials," since they are not in the medical best interests of some or all of their participants.[14] The exploitation in such trials is only potential because research participants can give free and informed consent to participate in them. Altruistic research participants are not necessarily victims of exploitation. But matters look very different if the participants are under a therapeutic misconception and falsely believe that they are receiving innovative therapy instead of serving the aims of clinical research.

The concern over the therapeutic misconception in clinical research points to a related issue that is relevant to the present discussion. In some of its original formulations, the therapeutic misconception was identified with both a false belief and a failure to make accurate risk/benefit assessments. Working with these two ideas, a systematic review of the data on the prevalence of the therapeutic misconception among research participants from 44 clinical research studies found it to be prevalent.

> Our findings show that 31.1% of participants expressed inaccurate beliefs regarding the degree of individualization of their treatment, while 51.1% manifested an unreasonable belief in the nature or likelihood of benefit, given the methods of the study in which they were enrolled. A total of 61.8% of participants were judged to have a TM [Therapeutic Misconception] on one or both of these bases.[15]

The authors of this review took evidence of unreasonable expectations of benefit from trial participation as an indicator of the therapeutic misconception. This decision has the potential to mislead. As the authors acknowledge, misestimations of risk and exaggerated expectations of benefit can occur for multiple reasons.[16] For example, these mistakes could result from simple failures on the part of investigators to disclose risk/benefit

[12] Exploitation, as understood in this essay, occurs when one party plays on some weakness or vulnerability of another party in order to get that party to serve his interests or ends. See Allen Wood, "Exploitation," *Social Philosophy and Policy* 136 (1995). Exploitation can be done in the service of valuable ends, as when a researcher exploits trial participants to further her goal of generating knowledge to combat disease.

[13] Clinical medicine does not always go well. Physicians can be incompetent, and they are subject to various principal/agent problems. I return to this issue later.

[14] Lynn A. Jansen, "A Closer Look at the Bad Deal Trial: Beyond Clinical Equipoise," *The Hastings Center Report* 35, no. 5 (2005): 29–36.

[15] Paul Appelbaum and Charles Lidz, "The Therapeutic Misconception in Clinical Research: Frequency and Risk Factors," *IRB* 26, no. 2 (2004): 1–8. (I have edited this summary to remove N numbers, etc.)

[16] Ibid.

information. This means that errors of risk/benefit assessment may occur, even when the therapeutic misconception is not present.

In a series of studies, I and my colleagues found that many research participants in early phase oncology trials are under the sway of an optimistic bias.[17] This bias, which is commonly referred to as "unrealistic optimism," has been widely studied in social psychology. Unrealistic optimism is not a general disposition to look on the bright side of things. Rather, it refers to an event-specific bias whereby people believe they are less likely to experience negative outcomes and/or more likely to experience positive outcomes than similarly situated others. It is a bias insofar as it interferes with the rational appreciation of risks and benefits. In our studies, we found that this bias was not correlated with the therapeutic misconception, where the therapeutic misconception was understood in terms of a failure to understand the purpose of the research trial. We inferred that the optimistic bias was an independent source of errors of risk/benefit assessment among the research participants we studied.

My point in mentioning this bias here is to bring out the challenge that it presents to the standard account of informed consent. The therapeutic misconception was taken to compromise informed consent insofar as it represents a failure of understanding, which is a key element of informed consent on the standard account. But if biases, like the bias of unrealistic optimism, engender a similar effect, namely a failure to appreciate relevant risk/benefit information, then they too should evoke ethical concern. Two issues now arise. First, research participants who manifest the optimistic bias do not lack capacity. Biases are prevalent in human psychology, and if they were taken to compromise capacity, then few patients would have capacity.[18] Biases also do not compromise understanding. People with unrealistic optimism often understand fully the risk/benefit information that is presented to them. They just fail to apply this information to themselves in a rational way. Biases also do not result from failures of disclosure, and they are not the products of voluntariness-impairing interference from others. So, if we want to say that biases can compromise informed consent in the research context, we will need to appeal to some additional standard.[19]

[17] Lynn A. Jansen et al., "Unrealistic Optimism in Early Phase Oncology Trials," *IRB: Ethics and Human Research* 33, no. 1 (2011): 1–8; Lynn A. Jansen et al., "The Impact of Unrealistic Optimism on Informed Consent to Participate in Early Phase Oncology Trials," *IRB: Ethics and Human Research* 38, no. 5 (2016): 1–7; Lynn A. Jansen et al., "Variations in Unrealistic Optimism Between Acceptors and Decliners of Early Phase Cancer Trials," *Journal of Empirical Research on Human Research Ethics* 12, no. 4 (2017): 280–88. (DOI: 10.1177/1556264617720433 | First Published July 21, 2017).

[18] The ubiquity of biases in our everyday thinking, and their constructive as well as destructive impact on our decision-making, is a central theme of Daniel Kahneman's influential *Thinking, Fast and Slow* (New York: Farrar, Straus, and Giroux, 2013).

[19] What to call this additional standard? In an earlier paper I argued that biases that interfere with the rational processing of risk/benefit information could be depicted as internal voluntariness-impairing factors. See my "The Problem with Optimism in Clinical Trials," *IRB Ethics and Human Research* 28, no. 4 (2006), 13–19. In that paper I sought to find a place for biases within

The second issue concerns why we should care about the impact of biases on informed consent. In many contexts, we should not care. Many couples contemplating marriage may be unrealistically optimistic with regard to the likelihood that their marriage will end in divorce, but few would think that this vitiates their consent to marriage. Relatedly, if Ellen has an unrealistic assessment of the risks involved in *Routine Procedure*, then no one should lose too much sleep over this. My claim is that biases among patients should not evoke the same concern as biases among research participants, since the former are not subject to potential exploitation in the way the latter are. For this reason, it might be a good idea for Institutional Review Boards (IRBs) to ask researchers to screen potential research participants for biases, if there were good instruments available for doing so. But it would not be a good idea to set up a regulatory board requiring physicians to screen their patients for these same biases.

These two issues require a good deal more discussion. I am advancing them for illustrative purposes. They suggest why we might have reason to have one set of standards for clinical research and another set for clinical medicine and why regulatory mechanisms for one context may not be appropriate for another. Thinking about biases and how they may affect informed consent thus provides some support for the idea that in biomedicine we should move from articulating a doctrine of informed consent to constructing models of informed consent.

III. The Normative Functions of Consent

Models of informed consent can be understood as pragmatic constructions designed to improve the practice of informed consent in the domains to which they apply. One concern someone might have is that it is not at all clear how we are to think about the normative content of the models we construct for different contexts. In contrast, a defense of the normative content of a doctrine of informed consent might seem to be straightforward. One just needs to think through how the background principle—respect for persons, autonomy, and so forth—applies to the practice of informed consent. But, in fact, I think that the models approach has an advantage on this score. We do better to view informed consent as serving a range of

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the standard general account of informed consent. But Paul Appelbaum has persuaded me that appealing to voluntariness is not a perspicuous way to accommodate biases, since voluntariness, at least in medical ethics, has always been understood in terms of external pressures. A better name for the standard we need is appreciation. See the discussion of appreciation as an element of capacity in Thomas Grisso and Paul Appelbaum, *Assessing Competence to Consent to Treatment* (New York: Oxford University Press, 1998). But some care must be taken in characterizing the relevant notion of appreciation. Biases of the sort I am interested in do not undermine the capacity to consent, but they do have the potential to compromise its validity. On the view I have in mind, appreciation is like understanding. It is an element over and above capacity.

normative functions as opposed to viewing it as an application of a background principle.

Let me briefly mention three such functions. The first one I will call the "protective function." One reason to insist on consent, and particularly informed consent, is to protect people, especially people in a vulnerable position, from being harmed by others. Discussing what he refers to as the "Hippocratic" conception of consent, Robert Veatch observes that this understanding of consent would be important even if autonomy were not a value.[20] This notion of consent, which is just consent that serves the protective function, is relevant to clinical medicine. For, as Veatch explains, medical well-being is a component of overall well-being, and it is this later notion that it is of primary importance. Physicians, who are experts on what is in the best medical interests of their patients, may set back the interests of their patients by failing to consider how medical decisions would impact concerns about their overall well-being. The requirement of informed consent provides a measure of protection to patients from this kind of mistake.

The distinction between medical well-being and overall well-being, I believe, is often less significant than these remarks suggest. Very often, the patient's primary focus is on her medical well-being, and there is no significant divergence between her medical well-being and her overall well-being.[21] In these common cases, to speak of her need to be protected from her physician is to misdescribe the situation. In the research context, in contrast, the protective function of consent looms large. The emergence of research ethics as a field of study, and the articulation of ethical guidelines for research in documents like the Belmont Report and the Helsinki Declaration, were a direct response to widely reported abuses in research practices. Infamous cases, such as the Tuskegee Syphilis Study, highlighted the need for research participants to be protected from researchers.

Some think that bioethicists have overreacted to these abuses. As I will explain, the protective function of consent, if pressed too far, can impede other functions of consent. But even so, it seems clear that the protective function of consent is more necessary and more pressing in the research context than in the context of clinical medicine. (Granted: abuses can occur in the clinical context, but they are more likely to occur in the research context since the researcher's professional interests conflict more directly with the interests of research subjects than do physicians' professional interests with the interests of their patients.)

A second normative function of consent can be called the "expressive function." In many spheres of interpersonal interaction, people have an interest in making decisions that reflect their personal values and concerns. We express who we are and what we stand for by the decisions we make.

[20] Robert Veatch, *The Basics of Bioethics*, 2nd edition (Oxfordshire: Routledge, 2002).

[21] For an opposing view, see Robert Veatch, *Patient, Heal Thyself* (New York: Oxford University Press, 2009).

Unfortunately, the expressive function of consent has led to much confusion in clinical medicine. It is important to distinguish a patient's claim to refuse treatment from a patient's claim to receive the kind of treatment he desires. Both claims are often thought to follow from a concern for autonomy. But the two claims have a different grounding. The claim to refuse treatment is a claim, in effect, to not be subject to battery by one's healthcare providers. It protects one's bodily integrity; and insofar as patients have an important interest in their bodily integrity it can be brought under the protective function of informed consent. In contrast, the claim to receive the treatment that one desires is justified, to the extent that it is, by expressive concerns. But these concerns are themselves limited by the beneficent aims of clinical medicine. A physician should not accede to the wishes of her patient if doing so conflicts with her duty to provide the patient with medically appropriate care. Expressive concerns, accordingly, must find a place within the space delimited by beneficent medical care.

Concerning participants in research trials, however, there is no such limit to the expressive function, since there is no duty of beneficence on the part of the research-investigator. This does not mean that there are no limits at all. Most research ethicists contend that ethical trials must satisfy some kind of fair risk/benefit requirement, although some view even this as objectionably paternalistic. What seems clear is that the expressive function of consent assumes greater importance in the research context than it does in the context of clinical medicine. If research participants are to be exposed to substantial risks of harm, then they should do so in large part because they are committed to the aims of the research, or at least to furthering the research project.

There is, lastly, a third normative function that I want to mention, one that can be called the "facilitative function." Consent makes possible valuable forms of interpersonal interaction and cooperation. The benefits realized by the consensual provisions articulated in contract law provide a clear illustration. However, the power of consent to facilitate these interactions is affected by the costliness and difficulty of securing it. This fact explains why there is often a tension between the facilitative function and the protective function of consent. By ratcheting up the standards of informed consent, we can better protect people, but by doing this we often will make it more difficult or costly to secure their consent. To think about how this tension should be managed, it may help to consider an example.

The 1972 court case *Canterbury v. Spence* raised the important issue of what kind of disclosure of medical information is required for informed consent. Mr. Canterbury had undergone surgery to repair a ruptured disc. The surgery was successful, but during recovery he accidentally fell from his bed, and the injury that resulted from this fall left his lower body paralyzed. He sued his physician, Dr. Spence, for failing to disclose to him the risk of injury from falling out of bed. In addressing the dispute, the court articulated a maxim to guide decisions about disclosure.

The maxim is that the patient should be informed of everything a reasonable person might consider to be relevant to his decision whether to undergo the procedure.[22]

Subsequent discussion of the court's decision, and the maxim it proposed, sought to clarify its content. Should relevant information be understood in terms of what medical professionals consider to be relevant, or in terms of what a reasonable patient might want to know, or in terms of some more subjective idea of what the patient, whether reasonable or not, would like to know? The discussion of this issue has tended to focus on what respect for autonomy requires. Once the issue is framed in these terms, there is pressure to move toward the more subjective requirement of disclosure. Patients with peculiar preferences, or unreasonable preoccupations, still have autonomy interests, after all.

But if we keep the other normative functions of consent in mind the issue can be reframed. Expecting physicians to anticipate all the information that any given patient might consider relevant to his decision making is not a costless requirement. It burdens physicians in a way that may not be reasonable. It may make more sense to demand less in terms of disclosure so as to facilitate the interactions between physicians and patients. This is not sacrificing informed consent for other values, but privileging the facilitative function over the expressive and protective functions.

Generally speaking, the facilitative function of consent will be more salient in contexts where the interacting parties share the same goals. If X and Y share the same goal, such as promoting the health of X, then it will be more important to facilitate their interaction than to provide protection for each against the other. In contrast, if X and Y have opposed goals or goals that do not align—X wants to promote his health; Y wants to advance his research—then greater weight should be given to protective and expressive concerns. The extra costs in terms of the facilitative function are worth paying.

If this is right, then the lesson to draw from *Canterbury v. Spence* is not the need for bioethicists to identify the stringency of the standard of disclosure that is required by the doctrine of informed consent or to derive it from reflection on the background principle of autonomy. The lesson to draw is that we should not expect there to be a general answer to the question that the case raised. The right way to think about the issue of disclosure is to ask what requirement of disclosure best fits the functions of consent that are operative in the case that one is considering. And, since in different contexts different normative functions of consent will be more or less important, the answer to the question will vary from context to context.

This point can be pushed even further. The right way to think about the requirement of disclosure will depend in part on the right way to think

[22] For discussion of the case see Ruth Faden and Thomas Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 133–38.

about the ontology of informed consent. If we accept the autonomous authorization view, we will likely demand a more stringent disclosure requirement. Patients cannot make autonomous decisions without information that bears on their values and concerns, however idiosyncratic they may be. But if we accept the fair transaction view, then we will be more amenable to less demanding requirements, particularly in contexts where demanding requirements would impose substantial costs on other parties.

Which view about the ontology of informed consent, then, is the correct view? Once more, there is reason to reject the question. The normative functions of consent should guide our thinking on the ontology of informed consent just as they should guide our thinking on the nature of its requirements. Don't expect a single answer here, we can say. Perhaps in the context of clinical medicine the fair transaction view is compelling.[23] Our discussion of *Routine Procedure* above suggested as much. In the context of human subjects research, in contrast, the autonomous authorization view of consent may be more appropriate. Wertheimer and Miller come close to conceding as much. In discussing the therapeutic misconception they begin by noting that on the fair transaction view of informed consent the comprehension of disclosed information is not required. But then they pull back.

> All that said, a fully developed account of FT [Fair Transaction] will probably require that investigators take affirmative steps to counteract TMs [Therapeutic Misconceptions] by clarifying the differences between research participation and medical care in their disclosures to prospective subjects, by avoiding language that conflates these two activities, by taking appropriate steps to ascertain whether key features of the research have been understood, and perhaps by signaling the distinction between research and treatment by paying patient-subjects at least a nominal fee for volunteering as a symbol that they are undertaking an activity different from medical care.[24]

These sensible recommendations can be anchored in the fair transaction view of informed consent, but they more naturally fit the autonomous authorization view. One can imagine circumstances in which the investigators have taken all the affirmative steps mentioned by Wertheimer and Miller and have discharged all their duties to screen for the therapeutic misconception among potential research participants. In doing so, they treat the research participants fairly, and thus on the fair transaction view informed consent has occurred. Yet suppose that in these imagined

[23] Disclosure requirements in clinical medicine thus could be viewed as requirements of fairness. To give a patient a fair opportunity to go forward or decline treatment, she must have access to relevant information, whether or not she actually attends to it. How much relevant information it would be fair to require physicians to disclose could vary with the type of medical decision under consideration.

[24] Wertheimer and Miller, "Preface to a Theory of Consent Transactions in General," 105.

circumstances some research participants still harbored the therapeutic misconception and were mistakenly included in the research trials. The autonomous authorization view can capture the thought that these participants do not give informed consent to participate. For this reason, it may be wrong to include them in the trial, even if the investigators are not blameworthy for doing so. This looks like the right result; but on the fair transaction view of the ontology of informed consent it can be secured only by building a mental state requirement into the terms of fair interaction.[25]

The specific points I have been making in this section are meant to illustrate a more general point. The different normative functions of consent can pull in different directions. In particular contexts, we need to think about which functions should be prioritized over others, and how to balance them when tensions are present. A general doctrine of informed consent is ill-suited for this task. Such a doctrine might be stretched so that it recommends different weightings of the different normative functions in different contexts, but this maneuver brings it close to the models approach that I am recommending.

IV. Blurred Boundaries

A preliminary case for my claim that we need two models of informed consent for clinical medicine and human subjects research has now emerged. Models of informed consent are pragmatic constructions that map the normative functions of consent onto different contexts of interaction. Rather than articulating a general doctrine of informed consent that applies to both medicine and research and then making ad hoc adjustments to accommodate differences that cannot be ignored, we do better to construct models for each context that differ in the standards that they impose, the stringency of the standards they share, the regulatory mechanisms appropriate for enforcing the standards, and even the ontology of informed consent itself.

Is this proposal workable? There is an important complication. The preliminary case I have made for two models of informed consent in biomedicine ignores the reality that medicine and research are not in practice separate activities, but ones that are deeply intertwined. Certain basic facts must be acknowledged. Institutionally, much of the research on human beings takes place in hospital settings and is undertaken by physicians,

[25] Imagine a research participant who resembles the patient Ellen in *Routine Procedure*. She is willing to consent to participate in a trial, has been given a fair opportunity to become informed about it, but does not want to be informed. Suppose that she should not be enrolled if the researcher conducting the trial knows that she is not informed. This is well explained on the autonomous authorization view, but hard to account for on the fair opportunity view. For this research participant like Ellen has been given a fair opportunity to become informed. For further discussion of this issue see my "Taking Respect Seriously: Clinical Research and the Demands of Informed Consent," *Journal of Medicine and Philosophy* 43, no. 3 (2018): 342–60.

who are often described as physician-investigators.[26] This reality has generated much discussion about how physician-investigators are to balance the conflicting ethical duties that come with their respective roles as physician and scientist.[27] And without question this institutional intertwinement itself plays a role in engendering and sustaining the therapeutic misconception.[28] But does it pose a deep problem for the two-models approach?

On my proposal, the contexts of clinical medicine and human subjects research are distinguished by their justifying purposes. Clinical medicine is oriented toward the best interests of the patient. Research on human subjects is oriented toward the goal of medical progress. While the institutional intertwinement of the two activities presents challenges for healthcare professionals, it does not make trouble for this way of distinguishing them.

A more serious challenge comes from the integration of beneficent medicine into the practice of clinical research.[29] This can occur in several different ways. First, research studies can test the comparative effectiveness of two or more standard medical treatments. Patient-subjects in these studies can receive clinical care that is as good, or better, than they would receive outside of the study. Further, the differences in the treatments that patient-subjects receive within the study may not matter to them. Second, clinical care can be incorporated into the design of a clinical research trial.[30] For example, a depression trial might test the standard drug for depression against the standard drug plus an experimental agent. No participant in such a trial is denied the treatment he or she would receive outside of the trial. Such a trial has both a beneficent purpose and a scientific purpose. Third, a research trial might offer participants a novel treatment option that is better than, or at least as good as, anything available outside of the trial. For some medical conditions no effective treatment is available; and access to an experimental drug may be the only option a patient has for combatting her disease.

This last possibility may be questioned. Research trials are undertaken to discover whether an experimental intervention is effective. Once the intervention is shown to be effective, ideally the trials should stop and the intervention should be made available to the general patient population. However, there may be a time period between the point at which the experimental agent in the trials has been shown to have some efficacy in

[26] Earlier versions of the Declaration of Helsinki (1964 and 1975) had separate guidelines for "Medical Research Combined with Professional Care (Clinical Research)" and "Non-therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)." The former category clearly manifests the intertwinement of medicine and research.

[27] The classic—and still very relevant —discussion of this problem is Charles Fried, *Medical Experimentation: Personal Integrity and Social Policy* (New York: American Elsevier, 1974).

[28] Rebecca Dresser, "The Ubiquity and Utility of the Therapeutic Misconception," *Social Philosophy and Policy* 19, no. 2 (2002): 271–94.

[29] Franklin Miller and D. Rosenstein, "The Therapeutic Orientation to Clinical Trials," *New England Journal of Medical Ethics* 348 (2003): 1383–86.

[30] Ruth Faden et al., "Informed Consent, Comparative Effectiveness and Learning Health Care," *The New England Journal of Medicine* 370, no. 8 (2014): 766–68.

combatting disease and the point at which the evidence for its efficacy is substantial enough to warrant stopping the trial and making the experimental agent available to patients as therapy. In this interim period, research-investigators could have both a reasonable therapeutic intent and a scientific purpose in conducting the trial. For example, late phase cancer trials may promise therapeutic benefit to cancer patients who otherwise have no treatment options for their disease. Patients who participate in these trials in the hopes of benefiting from them need not be exhibiting the therapeutic misconception.

What should be said, then, about practices where the boundary between research and medicine is blurred? What model of informed consent should apply to them? The authors of the Belmont Report claimed that if a trial contains any experimental component at all, as all trials must, then it should be considered research. The two-models proposal could help itself to this thought, but doing so would not fit with the underlying motivation for distinguishing the two contexts. That motivation, as I have been emphasizing, is the potential for a kind of exploitation that is present in one context, but not in the other.

In a provocative paper on informed consent in research, Gopal Sreenivasan invited his readers to consider a trial that bears on the issue we are now considering. The trial he imagined had a favorable risk/benefit ratio for all of its participants. The characterization of what counts as a favorable risk/benefit ratio is a little slippery, since it is common to include prospective benefits to society and to future patients within the benefit part of the ratio. But in Sreenivasan's trial the risk/benefit ratio is favorable, "even when direct benefit to the participant is the only benefit taken into account."[31] Sreenivasan argued that it would be ethical to conduct a trial of this kind with patient-subjects who were under a therapeutic misconception and had unrealistic expectations for benefit.

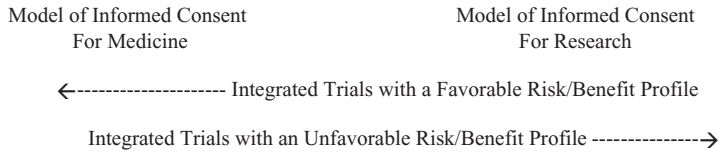
One might have doubts about the proposed example. Is it genuine? Would not a research trial present a degree of uncertainty that evidence-based clinical medicine does not? Perhaps a comparative effectiveness study could satisfy Sreenivasan's description. It would be a trial that a competent and beneficent physician could recommend to her patient, even if she had no concern for the scientific purpose of the trial. In effect, the physician would have the same mindset concerning her patient's participation in the trial as she would have concerning her patient undergoing a standard medical procedure, such as *Routine Procedure.* Her purpose in recommending trial participation to her patient would be entirely free of the exploitation concern that I have highlighted. The model of informed consent that is appropriate for clinical medicine, accordingly, would now seem to be appropriate as well for research trials of this imagined kind.

[31] Gopal Sreenivasan, "Does Informed Consent to Research Require Comprehension?" *Lancet* 326 (2003): 2016–18.

V. Sharpening the Divide

Do we have here a good challenge to the two-models account of informed consent that I have been advancing? The challenge blurs the boundaries of research and medicine by introducing a research trial that mirrors the medical best interests of the patient-subjects who participate in it. Such a trial would be both a scientific project and a therapeutic medical intervention. The key to trials of this kind, as Sreenivasan's description brings out, is the patient-centered favorable risk/benefit profile that they present to their participants. Standard medical care typically presents a favorable risk/benefit profile to the patients who receive it.[32] Mistake and ignorance can sometimes result in medical treatment that is not in the best interests of the patient, but the aim of medicine is to provide treatment whose prospective benefits justify its risks, if any. These observations suggest that the relevant distinction, on which the two-models account is based, is not between medicine and research, strictly speaking, but rather between the different risk/benefit profiles of these two kinds of biomedical interventions. Put another way, the precise divide that grounds the two models of informed consent is not the one between medicine and research, but the divide between practices that provide interventions that are in the medical best interests of participants from those that are not.

The precise divide maps onto the medicine/research distinction pretty closely, and it has the advantage of accommodating the kinds of trials that blur or merge the medicine/research distinction in ways that intuitively seem to matter. The diagram below illustrates the idea. Integrated trials are those that either combine research with therapy or purport to benefit their subjects. These trials can be divided into two basic categories: those that present and those that do not present a favorable risk/benefit profile for their participants.



[32] The benefit part of the risk/benefit profile must be assessed relative to an appropriate baseline. Sometimes the appropriate baseline is the risk/benefit profile provided by an alternative intervention, other times it is the likely outcome of receiving no intervention at all. Thus, a very risky procedure with only a small prospect for benefit can be favorable relative to the no-treatment baseline, which presents very grim prospects. Context should determine what baseline is the appropriate one.

Research is undertaken for its scientific purpose and potential to benefit future patients, but not for its potential to benefit trial participants. This makes it reasonable to place the burden of proof on those who claim that the trial they are conducting presents a favorable risk/benefit profile to its participants and so it appropriately engages the less demanding model of informed consent for medical practice. To meet this burden of proof it would not be enough to claim that the trial presents some prospect for benefit, such that a trial participant could reasonably hope that it was in her medical best interests to participate in it.[33] The investigator would need to establish that the experimental intervention presented a risk/benefit profile that approximated that of beneficent medical care. In practice, the precise divide I have proposed, when combined with the burden of proof requirement, might bring all trials other than comparative effectiveness studies under the model of informed consent for research. This would reestablish the initial distinction of the two-models approach. But the two-models approach allows, at least in theory and occasionally in practice, that some exceptional trials could appropriately engage the less demanding requirements of informed consent for clinical medicine.

The refinement that I have introduced to the possibility of trials of the sort proposed by Sreenivasan might be thought to open the door to further refinements. Trials differ in the risk/benefit profiles that they present to their participants. Concerns about exploitation intensify or wane depending on how unfavorable the terms of trial participation are for those who join them. With this in mind, some might reject the two-models approach on the grounds that it is not sensitive enough to the different contexts presented by different research trials. They might say that distinguishing two models of informed consent for biomedicine is a good start, but the introduction of further, and even more fine-grained, models would be even better.

In a parallel spirit, one might argue that my discussion of clinical medicine has been insufficiently sensitive to differences in context. I have claimed that clinical medicine serves the patient, and that medical treatment typically presents patients with options that have a favorable risk/benefit profile. But clinical medicine covers a wide range of cases. Sometimes physicians do not act in the best interests of their patients. Further, while many medical treatments are routine, some medical treatments present very high risks to their patients, and the prospect for benefit from them is uncertain or very low. Once again, one might argue, the lesson to draw is that further differentiations are needed.

The two-models approach welcomes this line of criticism. There is nothing special about the number two. But a further differentiation of models of informed consent requires articulations of salient features that distinguish the contexts and implicate the normative functions of consent in these

[33] Franklin Miller and Steven Joffe, "Benefit in Phase One Oncology Trials: Therapeutic Misconception or Reasonable Treatment Option?" *Clinical Trials* (2008): 617–23.

contexts differently. Recently, some writers have argued that consent standards in research should be adapted to risk. For high-risk research trials they propose a beefed-up consent process and for low-risk research trials they recommend "an abridged informed consent process."[34] This proposal could be extended to the models approach I have been advancing. Different models could be constructed for trials that present different levels of risk to their participants.

There are some reasons to be skeptical of such an extension, however. Classifying trials as high or low risk is often difficult in practice, and subject to controversy. This is not an insurmountable problem, but it makes abuse and mistake more likely. Researchers would have incentives to downplay the risks that their trials present in order to avoid being subject to more cumbersome consent requirements. This point is relevant since models are pragmatic constructions. They key the normative functions of consent to different contexts with the aim of improving the practice of informed consent.

A more principled consideration also tells against individuating models of informed consent on the basis of the risks they present to their participants. Trials that impose low risks can still present an unfavorable risk/benefit profile to their participants. These trials remain potentially exploitative, even if the harm they threaten is small. The divide between biomedical practices that are potentially exploitative from those that are not marks a difference in kind. In contrast, the difference between low-risk and high-risk trials is one of degree. And the difference in kind here matters. Consider the facilitative function of informed consent, for example. Those who argue for a streamlined or abridged informed consent process for low risk trials point to the need to reduce burdens on investigators. We should make it easier, they argue, for investigators to conduct valuable research. But the interaction here takes place under the shadow of exploitation, which taints the value of the interaction. Informed consent that meets the standards articulated in the model of informed consent that is appropriate for the research context removes the taint. The abridged consent proposed for low-risk trials may fail to do so.

These claims do not discredit the general idea of risk-adjusted informed consent. Within models of informed consent there is room for adjustment. Failures of appreciation and failures of understanding require cutoff points. For example, suppose that one thinks the therapeutic misconception invalidates informed consent in the research context. It is a further question what magnitude of this misconception triggers the invalidation, and to answer this question it is likely appropriate to consider the level of risk that a trial presents to its participants. The points I have made about risk-adjusted consent are meant only to provide some pushback against the proposal of

[34] Danielle Bromwich and Annette Rid, "Can Informed Consent Be Adapted to Risk?" *Journal of Medical Ethics* 41 (2015): 521–28.

differentiating models of informed consent solely on the basis of risk assessments.

My two-models proposal allows that within both of the models outlined in this essay some adjustment in the stringency of the standards of informed consent for different kinds of cases would be advisable. High-risk medical treatment should be subject to more stringent standards of disclosure than low-risk medical treatment, for example. With these treatments the protective and expressive functions become more salient, and the requirements for a fair opportunity to consent to such treatments should reflect this reality.

Perhaps someone might argue that for certain medical treatments risk-adjusted informed consent within the clinical medicine model is not sufficient. On this thought, high risk medical treatment with low prospects for benefit ought to be subject to the more demanding model of informed consent that is appropriate for the research context. Patients who are considering these treatments should be screened for biases that might adversely affect their decision-making, and regulatory boards similar to IRBs should be established to monitor the practice of their physicians.

These further steps would not be costless. They would impede the facilitative function of informed consent in clinical medicine, and I believe that they should not be undertaken unless risk-adjusted informed consent proved ineffective at protecting patients from mistake and abuse. Of course, there may be other challenges to the divide between the models that I have proposed, and we should be open to revising the boundaries between the two models if doing so can be shown to better serve the normative functions of informed consent. We should also be open to proposals for further differentiation of models informed consent. When and if these proposals were advanced, we would need to consider them in light of the normative functions of informed consent and the pragmatic value of constructing additional models.

V. Conclusion

I have been arguing that getting informed consent right in biomedicine is a good deal more complicated than its brief history would suggest. Much of the discussion of informed consent in medical and research ethics has labored to identify its key elements or components. Many have understood that some adjustment of the components is in order when applying informed consent to different contexts, like that of clinical medicine and research on human subjects. But this approach of applying a general doctrine and then adjusting has real limits—and it can lead us to overinflate the demands of informed consent in the medical context and not take these demands seriously enough in the research context. Turning from general doctrines to models of informed consent may provide a better way forward. Freed from the need to articulate a general account of informed consent, we can address issues about the ontology, standards, and regulatory

mechanisms of informed consent in a manner that is more sensitive to the underlying reasons that inform and justify its practice. The two models of informed consent outlined in this essay are mere sketches. They require refinement and development. My hope is that I have said enough about them to bring out the advantages of thinking in a different way about informed consent in biomedicine.

Center for the Philosophy of Freedom, University of Arizona, USA