Where Did Informed Consent for Research Come From?

Alexander Morgan Capron

As a starting point for this symposium on the future of informed consent in research and translational medicine, the editors suggested looking back to Judge Cardozo's famous opinion for the New York Court of Appeals in *Schloendorf v. Society of New York Hospital*, which recently passed the 100-year mark.[1] The notion that the future can be discerned by looking at what has come before — "what's past is prologue," as the Bard wrote[2] — is second nature to anyone trained in law, with our respect for precedent. In the present context, however, the need to examine the various sources for the modern doctrine of informed consent — "where did it come from?" — seems to me less a matter of deference than an essential analytic tool if we hope to understand "where is it going?" Consistent with the notion of anniversaries, I will pay special attention to several legal landmarks from 1947, 1957, 1972, and 1982 that all are now celebrating major birthdays.

I. A Hydrologist's Guide to Informed Consent in Research

For the past several years, most thinking — as well as a great deal of activity and anxiety —among academics and practitioners in our field about the ethics of research with human beings has been focused on the (frustratingly complex and opaque) process through which the federal regulations on research with human subjects were being revised.[3] Given that focus, events that took place 35, much less 70, years ago might well seem to be of little relevance compared with what was going on behind closed doors in Washington, D.C. and Rockville, Maryland. Ever since 2011, when the Office for Human Research Protections (OHRP) released an Advance Notice of Proposed Rulemaking (ANPRM) regarding the human subjects research regulations, commonly called the "Common Rule," and then in 2015 issued a Notice of Proposed Rulemaking (NPRM)—both of which prompted a tidal wave of public comments, most of them very critical — people concerned with the governance of human

Alexander Morgan Capron, LL.B., B.A., *is University Professor, Scott H. Bice Chair in Healthcare Law, Policy and Ethics (Gould School of Law), Professor of Medicine and Law (Keck School of Medicine), and Co-Director of the Pacific Center for Health Policy and Ethics, University of Southern California. He has served as chair of Public Responsibility in Medicine and Research (PRIM&R) and President of the American Society of Law, Medicine and Ethics and of the International Bioethics Association. An elected member of the National Academy of Medicine and the American Law Institute, Prof. Capron's articles and books address ethical, social, and legal issues in research and medical care, organ donation and transplantation, genetics, patient safety, and public health.*

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subjects research have been anxiously waiting to see how the regulations, which have been around for over 35 years, might be changed. Given the chorus of complaints about many aspects of the Common Rule that had become ever more audible as the years went by, one might have expected that a major redrafting of the Rule would have been welcomed. But when — on the last full day of the Obama Administration — the revised Rule appeared in the *Federal Register*,[4] what I heard from colleagues around the country was a sigh of relief that many of the biggest changes that OHRP had floated in the ANPRM and the NPRM had not been incorporated into the final version.

Despite all the attention that has understandably been aimed at the Common Rule of late, I plan to move away from the finer points of its sections that treat informed consent (particularly 42 C.F.R. §§ 46.116 and 46.117)[5] and to look instead at the doctrine's deeper sources. I want to suggest that we think

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of informed consent for research as a great lake, fed by three historical rivers. The headwaters of the first and oldest river arise from deep in the juggle of medical care, where physicians and patients encounter each other in the mysterious light that filters through the ancient trees of fear, hope, and discovery, tinctured by the near-magical powers of the healing arts. Traveling on this river can be difficult because its strong and swift currents often cut across each other with a rush of white water, one moment carrying our boat toward the swamp of medical paternalism, and then grounding it on an unexpected outcropping of individual autonomy. The second river begins in the city of Nuremberg, where judges bored deep into an ancient aquifer in search of the dividing line between licit research with human beings and experiments that amount to crimes against humanity. This river forks. One branch carries waters imbued with human rights law straight into the lake of informed consent, while the other meanders more slowly, devolving into professional standards along the way as it picks up some overflow from the first river.

The third river, which culminates in the Common Rule, begins at a large hot spring where problems in the conduct of human subjects research were sighted in the mid-1960s by an anesthesiologist from Boston. The subject became front page news when the revelation of the Tuskegee syphilis trials in 1972 caused the eruption of a geyser so huge that it blocked the sun over medical scientists and sent panic through the ranks of federal officials. Yet it turned out that similar problems had plagued research for more than one hundred years in experiments conducted with a lack of informed, voluntary consent. The river that runs from this third source — a river shaped by governmental regulations — is now much cooler than it was 45 years ago, though the occasional whiff of sulfur still remains. On the surface, its waters are clear but deeper down they can be turgid, and hidden currents can sometimes upend the boats — called IRBs (Institutional Review Boards) — that ply its waters as they carry stacks of paper and bags of money from the many agencies and drug companies lining its banks to the scientists who impatiently await their arrival.

I hope to use the picture I just sketched to explain my thesis. Simply put, I think we — especially those who are deeply involved with the Common Rule, like the IRB staff and members in those boats — have been too focused on navigating that third river. One result is that our sights have narrowed, as have the tasks that IRBs are expected to undertake. By 2000, Dr. Greg Koski, then the director of the recently reconfigured Office for Human Research Protections (OHRP), saw the need to overcome the adversarial relationship that had developed between the federal government and research institutions, as well as between those institutions (acting through their IRBs) and the investigators conducting research, regarding the way they carried out their research ethics responsibilities.[6] Unfortunately, in the past two decades not all IRBs have moved from the "culture of compliance" to the "culture of conscience" that he favored.[7] Indeed, concerns about regulatory compliance have evolved into a

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check-list mentality among many IRB members and administrators, focused on ensuring that every point in the federal regulations is translated into a box on a list of IRB duties and that every box on the list is marked off for each research protocol. And that in turn exposes the ironic effect of our whole research ethics review structure: it can actually divert us from attending to the basic ethical goals that were supposed to be the founts from which everything flowed.

My thesis is that achieving the goals of informed consent in medical research and translational science requires taking a much broader view of the topic. We need, of course, to be alert to the possibility that new research topics and methods will call for new means of seeking the goals of informed consent. But I also contend that we need to take a probing historical look at informed consent — in other words, we need to travel down those other two rivers, not just the one that begins with the 1974 National Research Act, which mandated that research institutions receiving federal research funds establish IRBs and charged the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research with elaborating the ethical foundations for research with human beings, including the expectations for informed consent.[8] The formula for research consent cannot be understood by testing the water in a single river, no matter how grand. It is to be found in the mingled waters of a lake fed by very different rivers.

Taking a broad view of informed consent will be important, I think, to the preservation of its core value. Today, biomedical research is becoming ever more closely integrated into the ordinary clinical activities of hospitals and physicians' offices. As I will elaborate below, that shift can be expected to erode consent if we're not careful. Further, more is heard from authoritative figures about individuals having "an obligation to participate in research"[9] which, taken to its logical conclusion, would dispense with informed, voluntary consent. One helpful way to respond to these and other issues is to take a journey along the other two rivers. So, let's begin.

II. Consent to Standard and Innovative Medical Care

Medicine has a long tradition of trying to protect patients, both through adherence to the high-minded ethical precept of always putting a patient's interest ahead of all else, especially the physician's interest, and through multiple stratagems that aim to induce in patients a childlike compliance with the course of action the physician regards as best suited to achieve the patient's interest.[10] Many commentators interpret this stance as the nearly inevitable consequence of sick people being too ignorant and too anxious to participate in decisionmaking about medical interventions. My friend and mentor Jay Katz argued instead that the silence between doctor and patient originates with physician's deep anxieties about their own fallibility — which are made worse rather than relieved by the availability of ever more powerful biomedical technologies — and an educational process that makes them jealous possessors of the authority that expertise can bring.[11] Sharing decisions with patients would force them into an uncomfortable examination of these and related factors that they would rather not confront.

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A. The Interest Protected: More Than Avoiding Harm

For a very long time, the law did little to engage directly with such underlying issues. But this does not mean that as a formal matter the law had nothing to say on a basic aspect of the relationship of physician and patient, namely, that physicians need their patient's consent to undertake medical interventions, especially surgery. This is not merely a latter-day concept but something well established in the law. For example, the requirement that a physician or surgeon obtain the patient's consent was explicitly stated more than 350 years ago in the Duke of York's laws of 1665, the founding legal document for New York, which was based on contemporary English common law.[12] Some commentators, such as Franklin Miller, have suggested that custom gave physicians a license to act without the patient's consent, at least when there was no perceived risk of harm.[13] The New York law of 1665, for example, raised the prospect of punishment for actions that are to "the prejudice or hazard of the Life or Limb of man, woman, or child." One might suppose that the consent requirement it imposed did not apply to less risky interventions. Just as is true today, at many moments within a relationship between doctor and patient, consent is implied rather than formally sought and provided. Compliance and acquiescence, that is, the absence of objection, provide a form of consent, in medicine as in the rest of our lives.

But I read the history differently, both as to the need for consent and as to the interest at stake, which was not narrowly protection against physical harm. The heart of the consent requirement can be found in the cause of action that patients brought when, they alleged, consent was absent. That cause of action embodies the precept that, just as a man's home is his castle, his body is his temple, and no one — not even a priest of medicine — may enter without his consent. The common law framed the absence of consent to medical interventions as cases of trespass — not trespass to real property (called *trespass quare clausum fregit*) but bodily trespass (*vi et armis*). A physician who provides medical care with the best of intentions but without the patient's consent may be horrified to be classed with a person who punches someone else in the nose, but each involves an unconsented touching and hence amounts to battery, a type of trespass.

Even were no physical harm to ensue, such a touching would amount to a dignitary harm. However, only in the most unusual circumstances (involving some outrageous element) are attorneys likely to counsel patients to file an action for the dignitary harm, namely, the physician's failure to respect the personhood of the patient, just as they would be unwilling to file for trespass against someone selling products door-to-door who walked up your front steps and knocked on your door without permission (or even ignored your "no solicitors" sign). The plaintiff in these cases is unlikely to recover more than nominal damages in the absence of physical (or economy) injury, which makes such cases not worth bringing.

Because of this practical reason for pursuing actual rather than merely nominal damages, the interest underlying consent is obscured. Further, rather than being raised as an independent cause of action, lack of consent is almost always alleged as an added claim in an action to recover for injuries sustained because of the physician-defendant's negligence. The law, very understandably, is protective of healthcare professionals as they face the challenge of applying their skills and knowledge; even an excellent exercise of professional skill does not guarantee a good outcome given the variability in human illness and in the bodies where it is manifest.[14] To recover, an injured patient must produce medical experts to testify that the defendant did not employ the learning and skill of a reasonable, competent practitioner in caring for the patient and that such malpractice was the cause of the harm suffered.

Since the law makes proving malpractice more difficult than establishing ordinary negligence, patient-plaintiffs commonly claim that the harm they suffered arose not merely from medical missteps but also because the physician-defendant failed to obtain valid consent from the patient. But even though the latter claim may be lack of consent, it is typically only brought because of the physical (or mental) injury that was allegedly caused by the medical intervention. Further, in analyzing the plaintiff's consent claim in such cases, it is hardly surprising that judges give the impression that the purpose of requiring consent is to enable patients to act as their own gatekeeper regarding whether to risk the potential harms of medical interventions — in other words, that consent exists only to protect again physical injuries. In fact, as this brief review of consent to medical care shows, the consent requirement is fundamentally a manifestation of one's right to decide not just which harms to avoid but more simply which interferences with one's body (or "touchings," to use the traditional formulation) to permit.

In contemporary discussions, we typically focus on the complexities of the "informed" part of informed consent, as will emerge in the sections below. But the principal point thus far concerns the ancient character of the headwaters of the river of consent for medical care, which long predate the creation of special consent rules for research.

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Continuing the journey down this river reveals five further points about consent for medical care with important consequences for research consent.

B. Self-Determination: Sweeping in Concept, Limited in Practice

The first point is the broad and emphatic language used in the cases on consent for medical care to describe what is involved. The notion of "self-determination" didn't just come into medical ethics and law in 1978 with the *Belmont Report* or, more broadly, with the early practitioners of bioethics who, beginning in the late 1960s, were determined to replace medical paternalism with patient autonomy.[15] Indeed, self-determination and related formulations of patients' rights have been part of the law of medical care for a long time. For example, in *Pratt v. Davis*, a 1905 Illinois appellate decision, Dr. Pratt admitted he had not told Mrs. Davis that to treat her epilepsy he was going to remove her uterus and ovaries. He defended his admission by asserting that "when a patient places herself in the care of a surgeon for treatment without [express limitations] on his authority, she thereby in law consents that he may perform such operation as in his best judgment is proper and essential to her welfare." In rejecting this claim, the court insisted that,

> under a free government at least, the free citizen's first and greatest right, which underlies all the others—the right to the inviolability of his person, in other words, his right to himself—is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent…to violate without permission the bodily integrity of his patient… and [to operate] on him without his consent or knowledge.

Nine years later, in *Schloendorf*, Judge Cardozo succinctly stated the same idea when he wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages." (It is worth remembering that this ringing endorsement of bodily integrity was delivered after the court had rejected the patient's claim against the actual defendant, the hospital at which she was treated, since it was not responsible for the surgeon's action and was protected by charitable immunity.)

Language of this sort at first glance suggests not a medical relationship but a civil one. The exaltation of liberty — of "thoroughgoing self-determination"[16] — sounds as though the courts thought they were protecting citizens from the state (or from each other) rather than respecting patients' right to make decisions about their medical care. Individual liberty is important in a democracy and very wide-ranging in its effects. It is both a shield defending individuals from outside control and a sword with which each person's agency, to be "a subject, not an object," is protected.[17] It is not something that others can usually waive on one's behalf.

C. Extending Consent Beyond the Body

Yet — in thinking about the implications for research consent — we also need to recognize a second point, that consent to medical care began with a strong focus on an individual's right to prevent an interference with his or her physical body. Thus, one needs to ask: what is the relevance of consent to activities that are separate from that body, such as examination or manipulation of stored tissues and cells or of medical records? The interest here is not adequately captured in the relationship between consent and protecting a person from *harm* — including non-physical forms of harm, such as reputational or economic harms — but rather protecting them against the *wrong* that occurs when they, as moral agents with the right and responsibility to chart their own lives and actions, are not given an opportunity to decide whether or not to accept an intervention involving their person or things intimately associated with their being.

D. Innovative Treatment Rather than "Research"

A third point from the early cases that make up the medical-practice river is that these cases did not directly concern research as that term is now used. When the cases did involve experimental procedures, it was in the context of what would today be called "innovative therapy," that is, departing from the usual course of treatment, typically because it isn't working, to try something that has not yet been established as effective. Indeed, the innovation may be a wholly novel idea of the physician employing it. Here, the early cases set a strict standard, holding physicians who departed from established methods of treatment liable for the adverse consequences of their actions.[18]

E. The Addition of the Physician's Obligation to Disclose

Up until now, the cases I've mentioned have all dealt with consent or its absence, not "informed consent." "Information" mostly arose as a concern in the earlier cases when the court considered whether a patient had been the victim of "false and fraudulent misrepresentation."[19] Merely stating what procedure would be performed was enough to provide the predicate for a

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valid consent, with no concern that the statement be sufficient to enable the patient to make an informed decision. That changed sixty years ago, when the term "informed consent" entered the legal lexicon.

The occasion was the litigation that arose concerning an imaging study and surgery performed by doctors at the Stanford Hospital on a 55-year-old man, Martin Salgo, who appeared to be suffering from advanced arteriosclerosis and occlusion of the abdominal aorta. Mr. Salgo underwent aortography, which confirmed the occlusion, but despite the surgical team's report that the procedure had been routine, the next morning he awoke with paralysis of his lower extremities, which proved to be permanent.

Mr. Salgo sued the hospital and the chief surgeon, and a jury awarded $250,000 in damages. On appeal, a California court of appeal reversed the judgment for the plaintiff. Most of the 1957 opinion discusses the trial judge's instruction to the jurors that they could find negligence based on the doctrine of *res ipsa loquitur*, in which negligence is inferred from the occurrence of something that does not ordinarily happen absent negligence. The appellate court pointed out that this doctrine only recently had been allowed in medical malpractice cases, and that the trial judge had failed to instruct the jury about how to apply it. Since the appellate court was sending the case back to the lower court for a new trial, the court also addressed the plaintiff's claim that the defendant surgeon had not explained "that anything in the nature of an aortography was to be performed" and the defendants' admission that "the details of the procedure and the possible dangers therefrom were not explained." The court stated that:

> A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent.

Yet, having set forth the duty rather strongly, the opinion wavered. First, it backed away from the newly created duty by accepting that a physician must sometimes withhold some information in order to fulfill his or her duty to place "the welfare of his patient above all else." Perhaps recognizing that this threatened to negate the new disclosure requirement, the opinion then stated that, while a physician may exercise "a certain amount of discretion," this "must be consistent with the full disclosure of facts necessary to an informed consent." Presumably both statements reflected the views, including the ambivalence, of the California Court of Appeals. However, in an ironic twist — given how aggravating many physicians seem to find the doctrine of informed consent — "[t]he entire informed consent paragraph in *Salgo* was adopted verbatim, and without attribution, from the *amicus curiae* brief submitted by the American College of Surgeons . . .."[20]

Over the subsequent years, courts struggled to figure how to treat a claim that a physician had failed to obtain informed consent. Was it properly brought under the heading of battery? If the failure to disclose the facts necessary for a patient to reach an informed decision rendered the consent invalid, then anything done to a patient would have been unauthorized and hence a legal battery. Or should a failure to obtain informed consent be treated as a breach of a professional duty, to be judged like all such claims on the basis of expert testimony that the defendant had fallen below the acceptable standard of professional practice by failing to make the disclosures that a reasonably competent physician would have made under the circumstances?

Fifteen years almost to the day after the *Salgo* decision, another California court settled the battery-vs.-negligence dispute in a new way. The case began with Ralph Cobbs being hospitalized for a debilitating duodenal ulcer. His internist recommended surgery and referred him to Dr. Dudley F. P. Grant, who performed surgery. Although the duodenal ulcer resolved, less than two weeks later Mr. Cobbs underwent a splenectomy due to severe hemorrhaging from a severed artery at the hilum of his spleen. A month later, he was readmitted because of sharp pains, which turned out to be caused by the gastric ulcer he was developing. When that did not respond to medical and dietary treatment, Mr. Cobbs underwent a gastrectomy, which involved removing 50% of his stomach, to reduce acid production. Shortly after being discharged, he was rehospitalized when he began to bleed internally due to the premature absorption of a suture. After a week in the hospital, the bleeding abated sufficiently for him to be discharged.

Mr. Cobbs sued the hospital and Dr. Grant for medical negligence in deciding to perform the initial surgery and carrying out the procedure improperly and for failing to obtain his informed consent. Dr. Grant admitted that he had not disclosed to the patient the risks of the various problems that actually arose, though all are known consequences. Mr. Cobbs received a $45,000 judgment against the hospital, which it paid. He also obtained a general verdict — that is, one which did not differentiate the two grounds for recovery, negligence and lack of valid con-

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sent — against the surgeon in the amount of $23,800, which Dr. Grant appealed.

In 1972, the California Supreme Court handed down its decision in *Cobbs v. Grant*. The court ruled for Dr. Grant, because the form of the verdict made it impossible to know whether the jury had found for the plaintiff based on Dr. Grant's failure to obtain consent or because he had committed medical negligence. Since the plaintiff had failed to produce at trial any expert evidence that either the decision to operate on the duodenal ulcer or the actual procedure breached the standard of care, a finding of medical negligence would have been without an evidentiary basis, so the entire verdict had to be reversed. Since the issue of informed consent would arise at retrial, the Court decided to clarify the law on the subject. First, it held that in most situations, such as the case before it, a claim of absence of informed consent should be treated as sounding in negligence not battery. (A battery action could still be brought if, for example, a surgeon obtained a patient's consent to perform one type of operation and instead performed another.) Yet the court then went on to hold that the usual rule in medical negligence cases—that the plaintiff must produce expert testimony which would support the conclusion that the defendant had departed from what a reasonably competent physician would have done under the circumstances — was not the correct standard for resolving a claim of failure to disclose enough information to permit the patient to provide an informed consent. Instead, the standard to which physician-defendants would be held in judging the adequacy of the information that they disclosed when obtaining consent would be set not at what physicians ordinarily disclose, but by what would be material to a patient in making a decision about the recommended treatment.

Sixty years ago, with the *Salgo* decision, the river of consent to medical care emerged from the dark forest of physician paternalism through which it had always run. Yet, for the next decade and a half, the ambivalence in the *Salgo* court's opinion meant that the river's current remained choppy, as other courts interpreted and applied the new concept of informed consent and in the process added or removed large boulders from the riverbed. With *Cobbs* and two other 1972 landmark decisions that also rejected the so-called "customary standard" of medical malpractice in favor of a standard for disclosure based on the patient's need to know,[21] the river rounded a bend and flowed in a new direction. Yet the river did not become placid because those cases opened up a range of interesting legal issues, such as the difficulties of proving causation in informed consent litigation and the problems in figuring out which information should be regarded as "material" to patients' decisions in various circumstances. On the latter issue, the 1972 decision in *Canterbury v. Spence*, for example, gave mixed signals. On the one hand, the court insisted that the scope of the risks that physicians must disclose "is not subjective as to either the physician or the patient" but rather objective, namely, the information that an average, reasonable person would want to know. On the other hand, it also stated that the "reasonableness" of what is divulged should be set according to what a physician "knows or should know to be the patient's informational needs."[22]

Moreover, this new direction for the river was soon weakened from a torrent to a tributary, as medical societies in many states — acting like the Army Corps of Engineers when faced with a wild river that could flood the homes and businesses along its banks — successfully lobbied lawmakers to adopt limiting provisions, as part of "tort reform" legislation. These provisions reversed or foreclosed judicial adoption of *Cobbs*-type rules, by legislating deference to physicians' custom in revealing (or concealing) information, rather than allowing a patient-centric standard of materiality to govern disclosure.[23]

F. The Gap Between Theory and Reality

I will close our trip down the river of clinical informed consent by drawing a fifth lesson, which is how far short the doctrine of informed consent has fallen from achieving its principal objective of getting patients engaged as active, informed decisionmakers about their medical care. Part of this problem can be laid at the feet of judges who, as the *Schloendorf* opinion so dramatically illustrates, have long been more inclined to make grand statements about patients' rights than to actually hold physicians — as fellow professionals — responsible for informing patients and respecting their choices. One particularly striking way that judges have done this is by allowing physicians to "refrain from making a disclosure that could so seriously upset a patient that it would be countertherapeutic,"[24] an exception that can easily swallow up the rule of informed consent. Even in *Canterbury*, Judge Robinson felt it necessary to leave the door ajar for this "therapeutic privilege," though he drew the line at physicians remaining silent "simply because divulgence might prompt the patient to forego therapy the physician feels the patient really needs."[25]

More fundamentally, physicians seemed to regard the new standard for disclosure as an annoyance rather than a goad to reexamine their communication with patients, much less an invitation to help their patients to understand their medical care within the context of their life stories and the choices they make.

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Thus, while the sunlight of self-determination has from time to time warmed the surface of the river of consent to medical care, below the surface its waters retain the ancient hues of medical paternalism. After surveying the other two rivers, we will come back to consider the effects these waters have when they flow into the lake of research informed consent.

III. Human Rights and Informed Consent in Research

The other two rivers are much younger than the first. The one that flows from the German town of Nuremberg originated only 70 years ago. "The Medical Case" that was tried between December 9, 1946, and August 20, 1947, before a tribunal of three American judges under the international law adopted by the Allied Powers at the end of World War II, is familiar as a singular moment to everyone interested in research ethics. The singularity arose first from the horrendous crimes of which the defendants (a number of them, highly respected members of the German medical elite prior to the war) were accused; these crimes included conducting deadly experiments on concentration camp inmates, killing Jews for anatomical studies, and mass murder of sick and non-Aryan persons under the guise of "euthanasia" (literally "good death"). Second, the singularity stems from the uncompromising nature of the "Nuremberg Code," as we now call the portion of the final judgment against the defendants in which the tribunal set forth the "moral, ethical, and legal concepts" that distinguish legitimate medical experimentation with human beings from the war crimes and crimes against humanity for which the defendants were on trial. Nothing in the Code is more categorical than its opening principle, "The voluntary consent of the human subject is absolutely essential," to which the judges added that this means that the subject "should be so situated as to be able to exercise free power of choice,…and should have sufficient knowledge and comprehension of the elements of subject matter involved as to enable him to make an understanding and enlightened decision."[26]

To appreciate the contribution of the Nuremberg Code to contemporary ethical and legal understanding of informed consent, we would do well to remember that it was a criminal law response to unethical research practices. I think this will point our boat — as we go down this second river — toward a couple of important questions: First, why, for the first twenty-five years after 1947, was the Nuremberg Code largely ignored by physician-investigators? And second, does the Code, with its strong commitment to voluntary informed consent (even in research supported by the state) remain relevant today?

The defendants in the Medical Case (or "Doctors' Trial," as it is also known) were accused of using unconsenting concentration camp inmates in many types of unethical experiments on diseases such as typhus,[27] malaria, and epidemic jaundice, as well as on the effects of ingesting poisons and salt water, of exposure to simulated high altitude conditions, and of lengthy immersion in freezing water. These acts could have been prosecuted as violations of law on the statute books of the Weimar Republic, which were not repealed under the Third Reich. Those laws can be traced back to 1900, when public outcry arose over the revelation in Prussia of experiments in which physician-investigators had given members of vulnerable populations (such as the poor, orphans, etc.) venereal diseases, without their knowledge or consent and sometimes with fatal results. The Prussian health and education ministry promulgated regulations that required that researchers obtain subjects' voluntary consent and that ruled out research on certain population groups, such as minors. In the 1920s, when renewed concerns arose because of new instances of unethical medical research, the Weimar government adopted legislation prohibiting the same sorts of practices.

But, rather than being charged with violating these German statutes, the defendants in the Medical Case were charged under international law. They raised several defenses. First, they individually tried to show that they did not participate in the acts charged; several of the defendants were in fact acquitted. Second, they argued that they were obeying directives from legitimate authorities which they were therefore obligated to follow. This "Superior Orders" defense has a mixed history in international law, but the London Charter of the International Military Tribunal, adopted in August 1945, had rejected the defense, although the charter allowed obedience to a superior officer's order to be considered in mitigation of punishment when the defendant demonstrated that he or she acted out of fear or was otherwise coerced. Third, and most relevant, the defendants argued that what they had done was part of "normal science." Underlying this argument — and closely aligned with "superior orders" — was the claim that people engaged in defense of their country during wartime can take steps that would otherwise not be permitted. For example, the defense attorney for the lead defendant, Dr. Karl Brandt, analogized his client to the pilot of the plane that dropped the atomic bomb on Hiroshima (which resulted in huge loss of life for noncombatants): that person committed what would otherwise be mass murder because he followed an order that aimed to bring the war to an end and thus to save his nation further harm and the risk of defeat.

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To rebut this line of defense, the prosecution presented evidence that even during wartime the research with human beings carried out in other countries in support of the war effort had remained ethical. The main witness on this point was Dr. Andrew C. Ivy, who ended up presenting both the results of his own study of this topic and the text of an American Medical Association statement on ethical research. He was asked:

> **Q:** In order to substantially carry out your position in the American Medical Association and in the Committee as appointed by Governor Green of Illinois [to consider the ethics of wartime research with prisoners at the Stateville prison], did it become necessary for you to exclusively (*sic*) study the conditions surrounding all the other experimental programs and services in medical history in order to ably devise rules of medical ethics to be applied in the course of medical experimentation on human beings?
> **A:** Yes, I had to see what the common practices have been.[28]

In other words, Dr. Ivy said he derived the standards from studying "all" prior research to determine "the conditions under which human beings have been used as medical subjects in cultured and civilized nations throughout the world."[29] (On cross-examination, it emerged that the statement of principles was not a document of long-standing but one he prepared after he took on the role of prosecution expert; the statement was submitted to the House of Delegates of the American Medical Association, for its approval, shortly before the trial began.)

At the heart of his testimony on the "procedures followed in the United States" was the claim that "Principle No. 1" is that "the consent of the subject must be obtained; also subjects must have been volunteers in the absence of coercion. Before volunteering the subjects have to be informed of the hazards, if any. Small rewards in various forms have been provided as a rule." Yet we know that Dr. Ivy's description of this as an ethical principle that has prevailed in "cultured and civilized nations" was inaccurate since it ignored a great many experiments conducted at the end of Nineteenth and beginning of the Twentieth Centuries without consent. These included not only the infection of female charity patients and orphans with syphilis and gonorrhea (which had prompted the Prussian regulations) but a long litany of sometimes deadly studies conducted by American and European physicians on prisoners, the poor, colonial subjects, and patients about which Dr. Ivy had to admit ignorance when cross-examined by one of the defendants, Dr. Gerhard Rose.[30] Moreover, the yellow fever research carried out by the U.S. Army in Cuba, in which the investigators stopped self-experimentation after one of them died, involved a large payment in gold — rather than a "small reward" — for the U.S. soldiers and Spanish laborers who were then recruited as volunteers, especially for those who contracted yellow fever or died. Finally, the researchers in charge of the Tuskegee syphilis study took active steps to disguise the existence of the study from the poor Black farmers in Alabama who were its subjects.

What is significant about this is neither Dr. Ivy's veracity nor the adequacy of his review of prior research with human beings, but rather that the judges were mistaken when they concluded that "the great weight of the evidence" established that "medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally."[31] The tribunal did not seem to recognize the tension that exists between medical ethics, which begin with the patient-centered injunction "primum non nocere," and the inherent risk that human beings will be harmed in research for the benefit of science and society rather than themselves. But the gap between the tribunal's model of ethical research and reality existed on the other side as well. Researchers in the United States prior to and during World War II — and even more afterwards when the federal government ramped up support for biomedical research and investigators continued using the utilitarian attitudes bred during wartime[32] — made themselves, rather than their subjects, the judge of whether to enroll in research, especially when a strict application of informed consent would make enrolling subjects in experiments much more difficult or even impossible (*e.g.,* in pediatric or psychiatric studies).

Thus, the distance between what the medical experts persuaded the tribunal was the prevailing practice and what was actually the case provides the answer to our first question, why was the Nuremberg Code largely ignored by physician-investigators? It was ignored because it bore no relationship to how physicians behaved in either research or clinical care at the time.

When physician-investigators in the United States and Europe looked at the Nuremberg Code, they did not see themselves, they saw a criminal court's judgment on barbarians who had abandoned the ethics of their profession. They didn't see doctors working in university laboratories and hospitals, they saw Nazis working in concentration camps. "The prevailing view was that they were Nazis first and last; by definition, nothing they did, and no code drawn up in response to them, was relevant to the United States."[33]

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Yet, it was not simply that researchers in America and other countries were oblivious to the Code's provisions, it was also that its description of what ethical physician-investigators did was so far from what they and their colleagues actually did that they found it unconvincing — and terribly inconvenient. Indeed, in the one place where the Code was formally accepted, namely in the upper echelons of the federal government and especially the Pentagon, its requirements were translated into statements of what was expected of those carrying out research, which were then marked "Classified" and apparently not widely communicated to researchers. And when the Nuremberg standards did show up in contracts between the Department of the Army and universities, researchers objected that they would not be able to carry out the studies they were expected to do. Harvard Medical School, for example, persuaded the Army in 1961 to allow it to substitute its own standards for the ones the government had derived from the Nuremberg Code.[34] The task of drafting those principles on human subjects research was undertaken by Professor Henry K. Beecher, M.D., who in 1959 had published an essay, "Experimentation in Man" (written as a report to the Council on Drugs of the American Medical Association, and approved by it for publication),[35] in which he "articulated a rich conception of research ethics, although one in which consent played a secondary role."[36] In Beecher's view, the fully informed consent demanded by the Nuremberg Code may have been an ideal but was not achievable,[37] and its strict enforcement would cast considerable doubt "not only on the propriety of studying mental disease but also on the use of placebos, essential to progress on studies in which judgment is involved in decision."[38]

As a product of a trial of physicians being prosecuted under international law, it is not surprising that the heart of the Nuremberg Code was incorporated into human rights instruments, such as the International Covenant on Civil and Political Rights[39] and the Council of Europe's Oviedo Convention.[40] Still, while the Code did little to guide the behavior of post-war physician-investigators, its influence was not limited to the realm of law but extended to medicine. This influence was indirect: its existence served to spur the medical community to develop its own set of ethical standards for research with patients and volunteers. Those standards, the Declaration of Helsinki, first approved by the World Medical Association in 1964, were offered to fill the space created by the Nuremberg Code as a set of conditions for ethical research globally. As such, one might see them as flowing in the same riverbed as the Nuremberg Code, but I believe that the channel they occupy in fact runs closer to the first river — of medical practice — than to the river of international human rights. Moreover, the bracingly cold waters of Nuremberg were considerably diluted by the overflow from the clinical practice river where the old paternalism still predominated. Indeed, the original version of the Declaration stated separate ethical expectations for such matters as informed consent from volunteers and from "sick persons"; as to the latter, "freely given consent after…a full explanation" was only necessary to the extent that obtaining it was "consistent with patient psychology."[41]

It may seem odd to find merit in the Declaration, given that it represented a conscious watering down of Nuremberg's standards, but Helsinki had two good effects. First, it brought physicians face to face with the need to reconcile, or at least to confront the difficulties of reconciling, traditional medical ethics with research practices, in a document of their own making rather than one imposed by judges (albeit ones who had been guided — or misguided — by two American physicians in drafting the Nuremberg Code). Second, Helsinki is a "living" document in a way that the Code could not be.

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light of experience, which has occurred repeatedly — sometimes amid strenuous debate and criticism—over the succeeding five decades.[42]

IV. Federal Regulations for Research with Human Subjects

As we turn to the second question that I anticipated we would face on our trip down the Nuremberg River — does the Code, with its strong commitment to voluntary informed consent (even in research supported by the state) remain relevant today? — it is appropriate to move on to our final river. This is the river whose headwaters are fed by the hot springs of research scandals disclosed by Dr. Beecher in 1966 and by the Tuskegee revelation in 1972. Exposure of the Tuskegee syphilis trials led to new regulations in 1981 for what was then the Department of Health, Education, and Welfare (DHEW), followed by government-wide regulations in the form of the Common Rule in 1991, and to a revised Rule in January 2017, seven decades after the three American judges condemned the Nazi doctors.

To anticipate what we will find as we travel down this river, the answer is "No": signs of the existence of the Nuremberg Code are seldom seen in these federal waters. One might explain this absence by saying that the Code was undermined because the ethical failings among American researchers (as seen in the Beecher article and the Tuskegee revelations) contradicted the picture of "ethical science" presented by the medical experts in Nuremberg, thus casting doubt on the Code's foundation. Yet if the distance between proclaimed standards and reality was able to cast doubt on any document, it should have been the physicians' own Declaration of Helsinki, which was being violated even as it it was being written in the 1950s and adopted in 1964. Yet Helsinki's presuppositions and rules were very influential in the period after 1972. Though the Nuremberg Code was mentioned by commentators like Beecher when they criticized ethical lapses and was invoked in the opening section of the *Belmont Report* as "the prototype of many later codes,"[43] its strict precepts and orientation toward subjects' rights rather than medical deontology continued to be disregarded in favor of professional codes such as the Declaration of Helsinki .

That is not to say that detailed rules were not adopted by the government. Thanks to the National Research Act of 1974 and the bureaucracy's response to the recommendations of the National Commission, rules that are intended to ensure ethical research, including respect for informed consent, are now a central part of federal funding of human subjects research through the system of Federalwide Assurances, under which research institutions state that they will adhere to the procedures required by the Common Rule and the established ethical principles for research, such as those distilled in the *Belmont Report*.[44] Nonetheless, fulfilling the expectations for voluntary, informed consent does not seem guaranteed, in part because the "culture of compliance," mentioned earlier, can lead investigators and reviewers to follow a checklist approach to their work.

Probably because the regulations grew out of rules first promulgated in the 1960s in the context of the extramural research program of the National Institutes of Health, which is a scientific rather than a regulatory agency, they leave many questions unaddressed. For example, when the regulations are violated, should the penalties be limited to those implicit in the rules themselves, such as the freezing of federal funding to the institution, either for the study in question or more broadly, until all regulatory deficiencies have been addressed?[45] (Note one effect of the generalized nature of the "penalty" here: it creates a substantial disincentive against bringing ethical transgressions to light, given that a "whistleblower" will typically come from within the institution where a research project is being conducted; the institution — and the whistleblower's interests — could thus be very adversely affected by reporting the problem.) At the other extreme, should the Nuremberg Code be invoked to allow a criminal prosecution or a civil damage action for a violation of the ethical standards of research, especially if harm befalls research subjects?

A more basic issue about the Common Rule, both in 1991 and as revised in 2017, is that it continues the process that began in the 1950s of moving away from informed, voluntary consent as the *sine qua non* for ethical research with human beings. Ironically, ethicists have probably contributed to that movement by taking aim at the overly complex manner in which consent is typically sought, driven by the institution's felt need to ensure that all the mandated basic (and possible additional) elements of consent under the existing §__.116 of the 1991 Common Rule are covered in the consent form.[46] The doubts thus created — that it may often be impossible to elicit from subjects a genuine, knowing choice to enroll in a clinical trial or other research — naturally directs the attention of regulators, IRBs, and commentators toward other means for protecting such subjects.

The drift away from the commandment that "The voluntary consent of the human subject is absolutely essential" was accelerated by the promulgation of the Declaration of Helsinki, which was essentially a map to guide the discretion of the "intelligent, informed, conscientious, compassionate, responsible investigator," as envisioned by Henry Beecher. But that drift has been driven by other forces as well. One springs

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from the objection — voiced by Beecher and still frequently heard, as Franklin Miller has recently pointed out[47] — that the problem is not with the form or process but is simply that "fully informed" consent is only rarely obtainable. This then leads to the problematic conclusion that consent should be regarded as merely "an ideal of rational decisionmaking" rather than as an ethical norm which must be met in every instance.

A second current in the Common Rule river that has pushed the federal regulations away from treating consent as the center of research ethics arises from the ever-stronger claims being made about the necessity of vigorous medical research as the prerequisite for human well-being.[48] We are long past Hans Jonas's insistence that "progress is an optional goal, not an unconditional commitment" and that "a slower progress in the conquest of disease would not threaten society,…but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having."[49] Instead, today even long-time advocates of informed consent are among those who look to a new paradigm of ethics for research.[50] Rather than starting from the essential nature of informed consent in research, the new paradigm implies that patients (out of gratitude for past research and as beneficiaries of the "learning health care systems" where they are treated) have a duty to participate in research, at least as it is interwoven with their care.

Paradoxically, the thing that gives these forces their power to undermine the principle of self-determination is the Common Rule itself. The Common Rule and the earlier DHEW regulations from which the Rule slowly emerged[51] were created at a time when bioethicists were attempting to replace medical paternalism and professional dominance with shared decisionmaking, in which patients, closely advised by their physicians, control the ultimate choices about treatment and research. But in addition to setting forth detailed requirements about the form and content of informed consent, the federal regulations also mandated that each research institution have at least one IRB, whose approval is needed before a research project involving human subjects may commence. In removing physician-investigators' authority to decide when and how patients should be enrolled in research studies, the National Research Act and the drafters of the regulations that implemented its IRB requirement[52] wanted to ensure that potential subjects would be enabled to make that decision for themselves, yet in creating IRBs to oversee the ethics of research, they made it possible to substitute a collective decisionmaker for the physician-investigator.

The revised Common Rule has continued to expand the range of research that can be carried out without prior consent by the individuals being studied. Yet, absent an IRB, these exceptions would have little effect, as a hue and cry would certainly arise if investigators on their own were empowered to impose a "waiver of consent" on subjects. It is the existence of the IRB that gives the waiver process life, since the board's decision to allow a study to proceed without prior consent — such as when strict adherence to the consent requirement would make it "impracticable" to conduct the study — is regarded as acceptable whereas the same action by a "conscientious investigator" never would be.[53]

Not all of the ideas that have been propounded regarding subjects' consent made their way into the 2017 Common Rule, but one major one did. The topic of "broad consent" has been extensively debated in the research ethics world for the past decade.[54] On the one hand, seeking permission to use samples and information from a person in future research, the methods and purposes of which are unknown when permission is given, fails to meet traditional notions of the sort of disclosure that is needed for consent to be "informed." On the other hand, requiring specific consent for each research use would effectively wall off collections of biological materials and associated data that many see as invaluable for advancing knowledge. The revised Common Rule contains a detailed process for getting "broad consent" for the storage and research use of identifiable biospecimens and private information, though exactly how this will work depends on further guidance from the regulators.

But the main point is not any particular provision in the federal regulations for human subjects research but the trend in those rules. As in much of the academic literature,[55] the trend has been to find reasons for dispensing with individual, voluntary, informed consent, especially when its necessity is doubted (as has long been argued for "low risk" studies[56]) or its feasibility is doubtful (because of the complexity of the research, which produces self-defeating consent forms that are too lengthy and complex to be understood). The supposed safeguard against such changes becoming abusive is, of course, that decisions about whether and how to proceed without subjects' consent will be made through a formal process with claimed transparency and oversight.

V. Navigating the Lake of Research Informed Consent

We have now traveled down these three rivers, explored their tributaries, and even ventured into some of the new channels that run alongside them. They all empty

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into the lake of research informed consent, whose waters are vital for human subjects research. I have not offered this image simply for its own sake but rather because I believe it allows us to get at something fundamental to our overall task, namely, understanding the future of informed consent. The activating feature of my metaphor is the three rivers. I have provided many details about how they were shaped and how they flow because I think their contributions to the lake water are at once important and, in the case of the first two rivers, easily overlooked.

My claim is that the distinctive characteristics of each informed consent river need to be recognized (and studied!) because of the effects that each has on the lake. For periods of time, the lake seems meromictic, with the layers of water created by the different river remaining separate. At the bottom are the cold waters that flowed from the deep human rights spring in Nuremberg; not only the temperature but the density and chemical makeup of this layer keeps it from regularly mingling with the waters above. The middle layer consists of waters from the oldest river, the one that originates in the physician-patient relationship. It is the one that mixes most freely with the others. Indeed, long before it reached the lake, some of its water flowed over its banks, mingled with some of the water from the Nuremberg river, and created another stream that eventually ran parallel, providing the Declaration of Helsinki's standards for biomedical research (including on consent) just as the main branch of this river provided the standards for clinical practice (including standards regarding consent). The location of clinical consent as a layer between the human-rights version of consent embodied in the Nuremberg Code and the regulatory version of consent embodied in the Common Rule is itself a metaphor for the fact that the regulatory version was a response to violations of the standards set by the Nuremberg not rules that evolved directly out of the Code.

The warmest water, in the top layer, derives from the Common Rule river, fed originally by the hot springs of research abuses identified in the 1960s and then by the Tuskegee geyser in 1972. These eruptions were supplemented by others — some old ones, which led to the first formal regulations of research with human subjects in Prussia and Weimar Germany, and a number of new ones, such as the revelations in the 1990s about the Cold War era experiments on ionizing radiation, and the sexually transmitted disease research conducted by the U.S. Public Health Service in Guatemala in the late 1940s, uncovered in 2010.

Most of the time, we glide across the top layer and rely on that experience to inform our understanding of when, how, why, and from whom to obtain informed consent. But we make a mistake if we take account only of the formal regulations that constitute that layer because our trips across it can sometimes be affected — or even upended — by things happening in the layers below. Take a simple example: we have long known that an overwhelming majority of the public does not think of informed consent as something that aims to make them better decisionmakers but rather as a means used by physicians to protect themselves against liability.[57] Instead of being a process of discussion that aims to reach a mutually agreed way forward, informed consent is equated with a document — the consent form. It is but one of a tidal wave of forms that patients sign (on paper or, increasingly, electronically) before being admitted to a medical facility, forms in which they attest to having been given certain warnings, told about their HIPAA privacy rights, asked if they have an advance directive, and so forth. Patients are right to perceive that the consent form is all about foreclosing liability. After all, they can see as much from the forms themselves, which usually run on for mind-numbing page after mind-numbing page, filled with avowals of the benefits of the study alongside descriptions of every bad thing that could possibly happen.[58] This means that the eventual act of signing such a form is often little more than a ritual, like clicking on "Accept" to download the newest App to one's smartphone.

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The salient point here is that a view of consent created in the clinical setting necessarily shapes how it is seen — by patient-subjects as well as physician-investigators — in the research context. Most people sign many more consent forms when receiving regular care than when taking part in research. Most of the litigation over consent, and most of the legislation aimed at resisting the "reasonable patient" standard of disclosure, arose in the clinical context. Indeed, the requirement of §__.116(a)(4) in the revised Common Rule —

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that the person from whom consent is sought "must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate" — was drawn from the clinical context and hence shares its confusion about when and why the law traditionally looked to the proverbial "reasonable person." Outside the medical context, law uses an objective "reasonable person" to announce the level of care that a person must use when conducting an activity with the potential to harm others. The "reasonable person" standard guides the jury in its retrospective determination of whether a defendant created only such risks as a person acting with due regard for the welfare of others would have created. In contrast, patients are entitled to have their own idiosyncratic grounds for deciding in favor of one treatment and against another and are not expected to choose "reasonably," much less be punished for failing to do so. Thus, physicians ought to be under a duty to enquire about the patient's wishes, values, phobias, etc., as they could relate to the medical decisions at hand, in order to ascertain what information would be "material" for the particular patient making a clinical decision.[59]

Although the information disclosed in the consent process for research must of necessity be more standardized than in treatment, the invocation of "the reasonable person" by §__.116(a)(4) of the new Common Rule suggests that investigators when developing, and IRBs when reviewing, what needs to be disclosed would be well advised to examine the history of, and problems raised by, that concept in the law on informed consent for treatment. This is an example of why we cannot understand what is happening in the lake of informed consent if we only look at the federal regulations. To understand how the new Common Rule will affect communication between investigators and subjects, we need to take account of medical law more broadly, which has aimed at shaping the manner in which physicians obtain permission to treat their patients. And even more important, we must remember how that law conflicted with the training and psychology of medical professionals, how organized medicine resisted judges' sweeping affirmations of patient self-determination, and how ready those judges were to wipe away the pictures they had painted of patients as informed decisionmakers before the inspiring portraits they had painted in their judicial opinions were even dry. If we do not take those realities into account, we will be beguiled into believing that these same medical professionals, when they put on their "researcher hat," will not behave in a manner that is normative in clinical care. Many may make the transition, but both experience and common sense suggest that not all (or even most) actually will.

Take another example: it is generally accepted that research is becoming a more prominent part of medical practice, whether in the "learning from every experience" guise (in which the results of routine care within healthcare institutions are carefully analyzed), in the incorporation of clinical trials into medical care (in cutting-edge fields where few cures exist and most interventions may be experimental), and in formal comparative studies of different treatments that are all regarded as meeting the "standard of care" for treating a particular condition. In all of these settings, the rules and expectations — on the part of physicians and nurses as well as patients — about what sort of disclosure and consent will occur are likely to be heavily shaped by what usually occurs in clinical settings, precisely because what is going on actually is clinical care.

Indeed, two prominent theorists of bioethics have recently argued that the "entrenched distinction between research and practice is both puzzling and morally questionable" because research and practice occur together as just described and because many medical techniques in common use have never been scientifically validated, which makes means they are "regarded, rightly, as experimental."[60] Rather than causing a visible upwelling of water from the middle (clinical care) layer into the Common Rule layer, the blurring of the research-treatment distinction is likely to result in an ill-defined mixing of the waters, with adverse consequences for those conducting research studies. This is illustrated by the SUPPORT dispute, where, in my view, the criticisms aimed at the researchers for inadequate informed consent really reflected shortfalls in the process by which the physicians sought (or failed) to inform the parents of the neonates being recruited into the study about the choices the parents would face in treatment, so they could appreciate how those choices would differ if their child was included in the study.[61] Of course, if the "central issue is whether research projects require a higher level of scrutiny" than clinical care,[62] one might just as well conclude that clinical care needs more scrutiny as conclude that research needs less.

The story of clinical informed consent contains another relevant lesson, one that concerns not the failure of the law to prevent harm when physician don't comply with the law but the law's failure, even when obeyed, to promote human flourishing. When, as is regrettably too often the case, physicians equate "informed consent" with a signature on a consent form or treat it as an isolated moment in their relationship with their patient, then the opportunity has been lost for the decision that the consent supposedly validates

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truly to be incorporated into the physician-patient relationship and, more broadly, into the patient's own narrative of his or her life. Physician and patient both have ideas, hopes, anxieties, needs, concerns, and the like regarding the patient's condition and what they can do together to improve it. Inevitably, they will reach decisions about which interventions should be tried — now, later, or never. Legally valid consent can (and ideally should) emerge as an integral part of the discussion that a physician has with his or her patient about care; it should not be regarded as something discrete, disconnected from that discussion.

The barriers to this happening, that is, to the legal requirement of disclosure becoming an invitation to discussion between physician and patient, originate, as Jay Katz argued, in the hierarchy of the relationship, which both parties reinforce for their own deeply held reasons.[63] But expectations can and do change. Patients who have gone online to research their conditions have more questions for their care providers; medical students are educated to embrace partnership with, rather than domination over, patients. And, ironically, while the research setting might seem a poor place to look for change, since research may sometimes involve only a brief interaction — for example, between an investigator and a patient enrolled in a randomized controlled trial of a new drug — much research, particularly on conditions that are chronic or life-threatening, leads to deep, involved relationships among the research team and the patient-subjects. To the extent that, as Katz also argued, physicians' failure to engage in conversation with their patients reflects conscious or unconscious discomfort over confronting their uncertainty about the patients' conditions and possible treatments, researchers are at an advantage. Admitting uncertainty does not undermine their authority because uncertainty is inherent in research. Indeed, to genuinely involve a patient in research is to make the resolution of that uncertainty a part of the patient's narrative of his illness and of his life. For Hans Jonas, such identification with the goals of research was the prime criterion for deciding which people ought to be research subjects.[64] And today, such engagement of patients in research is a core tenet of efforts (by the Patient-Centered Outcomes Research Institute and "translational research" centers) to place patients' experiences and needs at the center of research and to engage them in its design, execution, and dissemination.[65]

We have seen many reasons why the waters contributed by the river of clinical informed consent, emanating from the resolution of malpractice cases and from legislative responses thereto, can affect the federal research regulations that form our lake's upper layer. On the other hand, it seems more doubtful that the bottom layer, consisting of a human-rights approach to permissible research, as embodied especially by the Nuremberg Code, will rise from the depths to break the tranquility of the lake's surface. Indeed, I suggested above that the Code was first sidelined as *sui generis* — regarded as rules crafted solely for researchers operating on behalf of the Nazi state — and was then supplanted by the Declaration of Helsinki, which was presented not as stating the rights of humans when enrolled in research but as the obligations of physician researchers.

The barriers to this happening, that is, to the legal requirement of disclosure becoming an invitation to discussion between physician and patient, originate, as Jay Katz argued, in the hierarchy of the relationship, which both parties reinforce for their own deeply held reasons. But expectations can and do change.

Yet the very existence of the Nuremberg Code and related documents that take a human-rights approach to research subjects' informed consent serves as a reminder that rules are not always followed. Prior to the war, Germany had on its statute books a set of prohibitions on unethical research — particularly research conducted on people whose ability to provide informed consent was compromised — that failed to prevent the human rights abuses in the concentration camps. When driven by ideology and by a desire to promote the welfare of the general population, the defendants in the Doctors' Trial — who included well-known leaders of German medicine, which prior to the war represented the pinnacle of scientific medicine around the world — did horrible things, undeterred by that law. Their precise wrongs may never be repeated nor equaled. But if we ignore not just the strong rules that emerged from the trial but also the forces — be they competing loyalties, lack of respect for the populations from whom research subjects are drawn, or the general sense that physicians must be free to do what they think best — we are at risk of falling asleep as our boat floats along peacefully and then finding ourselves rudely awoken or even thrown overboard when some egregious research abuse causes a sudden upward

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movement of the deep waters that can turn the lake's surface from glassy smoothness to choppy waves.

That need not be our fate if we remain mindful of the effects that all three rivers can have on the ways that informed consent for research operates as their waters merge and separate. Not just investigators and IRBs but public officials, commentators, and scholars have good reason to concentrate on the portion of the lake of informed consent that originates in the Common Rule river. But equally good reasons exist for them to be mindful of the waters from the other two rivers. They should remember the ways in which travelling along the river of ordinary clinical care shapes the thinking and practices of patients and physicians and the ways in which a human-rights orientation toward research, as was visible in Nuremberg, challenges Hippocratic assumptions about beneficent physician-investigators. Informed consent under the federal regulations did not simply originated in 1974 with the National Research Act, so understanding its future necessitates studying the principles and problems that flow from the long history of consent (and its absence) in clinical care and from the judgment on the Nazi experimenters that we know as the Nuremberg Code.

Note

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6. "I believe that the current model is one that is largely confrontational in its foundation. It is a model that is focused primarily on compliance… Testimony of Greg Koski, Ph.D., M.D., before the National Bioethics Advisory Commission, Sept. 12, 2000, Washington, D.C., p. 196, *available at* <https://bioethicsarchive.georgetown.edu/nbac/transcripts/sept00/9-00day1.pdf> (last visited Aug. 22, 2017).
7. N. M. Goldfarb, "Greg Koski on Human Subjects Protection." *Journal of Clinical Research and Best Practices* 3, no. 9 (2007): 1-6, at 2, *available at* <http://www.firstclinical.com/journal/2007/0709_Koski.pdf> (last visited Aug. 22, 2017):

   > The OPRR inspections found deficiencies in meeting operational requirements set forth in the regulations. But when you have operational deficiencies, it raises questions about whether there are deeper problems … What the government had done was to create a process that, by and large, was going through the motions without any real evidence that, in fact, it was doing much good. As Dr. Koski explained, he "never believed that more regulation was the way to go." A "culture of compliance" was not what we wanted. We wanted to build a "culture of conscience" where people didn't do the right thing because it was required by the law, but because of their own sense of moral responsibility and personal integrity – because it was the right thing to do. We emphasized proactive approaches to prevent injury, rather than reactive approaches that would punish someone when something bad happened. Obviously, the goal was, and is, to prevent harm, not to react after harm occurs.

8. National Research Act of 1974, Pub. Law 93-348, July 12, 1974, Title II, Part A, §§201-205 [establishment and duties of Commission], and Part B, §212(a)[IRB review required].
9. *See, e.g.*, G. O. Schaefer, E. J. Emanuel, and A. Wertheimer, "The Obligation to Participate in Biomedical Research," *Journal of the American Medical Association* 302, no. 1 (2009): 67-72.
10. Jay Katz opens his pioneering examination of physician-patient communication by describing the belief of physicians since the time of Hippocrates, "'Good' patients follow doctor's orders without question." J. Katz, *The Silent World of Doctor and Patient* (New York: Free Press, 1984): at 1.
11. *Id.*, at 16-25 and 165-206.
12. Richard Nicolls, the first English Governor of the Colony of New York, oversaw the compilation of *The Duke of York's Laws*, drawn from the statutes of the other English colonies in America, which themselves reflected prevailing English common law on civil and criminal matters. Promulgated at Hempstead, on Long Island, March 1, 1665, the laws contained the following statement regarding punishing (as severely "as the nature of the fault may deserve") surgeons, midwives, and physicians who depart from professional standards or intervene without their patient's consent:

    > [No] Person or Persons…Employed about the Bed of Men women or Children at any time for preservation of Life or health as Chirurgions, Midwives, Physicians [shall] presume to Exercise or put forth any Acte…or Exercise any force violence or Cruelty upon, or to the Bodies of any whether Young or old without the advice and Counsell of the such as are Skillfull in the same Art (If such may be had,)…and Consent of the patient or patients if they be Mentis Compotes…to the prejudice or hazard of the Life or Limb of man, woman, or child.

    "CHIRURGIONS, MIDWIVES, PHYSICIANS" in *The Duke of York's Laws, 1665-75*, *available at* <http://www.nycourts.gov/history/legal-history-new-york/documents/charters-duke-transcript.pdf>, at 15 of 48 (last visited Aug 28, 2017).
13. F. G. Miller, "Consent to Clinical Research," in F. G. Miller and A. Wertheimer, eds., *The Ethics of Consent: Theory and Practice* (New York: Oxford University Press, 2010).

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14. The solicitude that the law has shown for medical professionals (e.g., the higher standard of evidence required to establish actionable negligence) doubtless reflects the experience of judges and lawyers in their own profession: the occurrence of an unwanted outcome when serious and complex legal problems are being resolved does not mean that the lawyer involved failed to exercise the skill expected of a competent professional. In the practice of law an added twist arises, which is absent in medicine, where a physician's opponent is an illness or injury — namely, that in legal disputes one side wins, the other loses, yet it cannot be the case that every legal action perforce implies that one lawyer has failed to exert the necessary skill or effort on his or her client's behalf.
15. Some twenty years later, Robert Veatch, an early, vocal proponent of using the doctrine of consent to replace medical paternalism with patient autonomy, concluded "that consent is merely a transitional concept," which "emerged in the field as a liberal, innovative idea" but whose "time may have passed and newer, more enlightened formulations may be needed," that would substitute a patient's exercise of active choice among alternatives for the whiff of "acquiescence" that accompanies "consent." R. M. Veatch, "Abandoning Informed Consent," *Hastings Center Report* 25, no. 2 (1995): 5-12.
16. *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093, *rehearing denied*, 187 Kan. 186, 354 P.2d 670 (1960).
17. *See* President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions*, Vol. 1 (Washington, D.C.: U.S. Government Printing Office, 1982): at 44-47, quoting I. Berlin, "Two Concepts of Liberty," in *Four Essays on Liberty* (Oxford: Clarendon Press, 1969): 118-138.
18. Physicians used new or untried methods "at their peril." *Carpenter v. Blake*, 60 Barb. 488 (N.Y. Sup. Ct. 1871), *reversed on other ground*, 50 N.Y. 696 (1872).
19. *See Hunt v. Bradshaw*, 88 S.E. 2d 762 (N.C. 1955) (concurring opinion of J. Bobbitt).
20. Katz, *supra* note 10, at 60. Professor Katz concludes that the ambivalence in the new doctrine of informed consent "has all the earmarks of a dream," recalled as one first awakes, in which impossible facts are joined together. In this case, the surgeons who advised the lawyers writing the *amicus* brief were — unconsciously rather than deceitfully, Katz believes — trying to reconcile the increased risk that the growing powers of medicine can harm as well as hurt with the reality that it is unlikely that most patients can actually provide "intelligent consent," as the *Salgo* opinion states. *Id.* at 63-65.
21. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *Wilkinson v. Vesey*, 110 R.I. 606, 295 A.2d 676 (1972).
22. *Canterbury v. Spence*, *supra* note 21, at 787. *See generally* A. M. Capron, "Informed Consent in Catastrophic Disease Research and Treatment," *University of Pennsylvania Law Review* 123, no. 2 (1974): 340-438.
23. *See* A. Meisel and L. D. Kabnick, "Informed Consent to Medical Treatment: An Analysis of Recent Legislation," *University of Pittsburgh Law Review* 41, no. 3 (1980): 407-564. A few states went further than restoring the medical custom standard and limited the obligation to a bare minimum disclosure of the risk of death or specified major injuries. *See, e.g.*, Louisiana Public Health & Safety Code, Sec. 40: 1299.40 (1975).
24. President's Commission, *supra* note 17, at 95.
25. *Canterbury v. Spence*, *supra* note 21, at 789.
26. *United States v. Karl Brandt et al.*, *Trials of the War Criminals Before the Nuremberg Military Tribunals under Control Council Law No. 10,* Vol. 2, Washington, D.C.: U.S. Government Printing Office (1949): 11374 (Aug. 19, 1947), *available at* <http://nuremberg.law.harvard.edu/transcripts/1-transcript-for-nmt-1-medical-case?seq=11523> (last visited Sept. 2, 2017).
27. Leo Alexander, an American physician who was one of the expert witnesses at Nuremberg, pointed out that the defendants' criminal attitude toward their inmate-subjects interfered with being successful researchers. During research to find a vaccine for typhus, pre-vaccinated persons and non-vaccinated controls were injected with typhus rickettsia. At some point, the strain being used became avirulent in humans. "Instead of seizing upon this as a possibility to develop a live vaccine," the experimenters were simply annoyed that the controls weren't dying, discarded the strain, "and continued testing their relatively ineffective dead vaccines against a new virulent strain." L. Alexander, "Medical Science under Dictatorship," *New England Journal of Medicine* 241, no. 2 (1949): 39-43.
28. *United States v. Karl Brandt* et al., *supra* note 26.
29. To buttress his claim of universalisability, Dr. Ivy testified on June 13, 1947, that the three principles he drew from his historical study (voluntary informed consent, well-designed research justified by anticipated results, and scientifically qualified investigators minimizing suffering and injury) could also be found in "a decree of the Minister of Public Welfare of Germany in 1931 on the subject of 'Regulations for Modern Therapy for the Performance of Scientific Experiments on Human Beings'." *Id.* at 9142.
30. *Id.* at 9253-9267 (June 16, 1947). Given the technical nature of the questions, the tribunal in the interest of time permitted Dr. Rose, rather than his counsel, to cross-examine the witness.
31. *United States v. Karl Brandt et al.*, *supra* note 26, at 11373, *available at* <http://nuremberg.law.harvard.edu/transcripts/1-transcript-for-nmt-1-medical-case?seq=11522 (last visited Nov. 26, 2017)>.
32. D.J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York: Basic Books, 1991): 51-69. Rather than making a philosophical choice of progress for the group over individual welfare, Renée Fox sees physician-investigators simply failing to examine the issue. Although memories of the Nazi experiments "were still hauntingly present," investigators in the 1950s and 60s were swept along by "the renaissance of medical research" which diverted them from "sustained brooding about the ethicality of human experimentation." R. C. Fox, *Experiment Perilous* (Glencoe, IL: Free Press, 1959): at 10.
33. Rothman, *supra* note 32, at 63.
34. J. D. Moreno, "Reassessing the Influence of the Nuremberg Code on American Medical Ethics," *Journal of Contemporary Health Law & Policy* 13, no. 2 (1997): 347-360.
35. H. K. Beecher, "Experimentation in Man," *Journal of the American Medical Association* 169, no. 5 (1959): 461-478.
36. F. G. Miller, "Henry Beecher and Consent to Research: A Critical Re-Examination," *Perspectives in Biology and Medicine* 59, no. 1 (2016): 78-94.
37. The idea that an investigator could enable a potential human research subject "to make an understanding and enlightened decision," as the Nuremberg Code expects,

> is often quite impossible…for the complexities of essential medical research have reached the point where the full implications and possible hazards cannot always be known to anyone and are often communicable only to a few informed investigators and sometimes not even to them.

Beecher, *supra* note 35, at 473.
38. *Id.* at 472.
39. United Nations General Assembly, *International Covenant on Civil and Political Rights* (1966): Article 7 ("No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."), *available at* <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CCPR.aspx> (last visited Sept. 16, 2017).
40. Council of Europe, *Treaty No.164, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention*

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on Human Rights and Biomedicine (1997): Chapter V—Scientific research, *available at* <http://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98> (last visited Sept. 17, 2017).

41. Editorial, "Declaration of Helsinki," *New England Journal of Medicine* 271, no. 9 (1964): 473-474.
42. *WMA Declaration Of Helsinki: Ethical Principles For Medical Research Involving Human Subjects* (most recently revised at the 64th WMA General Assembly, Fortaleza, Brazil, October 2013), *available at* <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (last visited Sept. 17, 2017).
43. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report* (1978): at 3.
44. A further set of ethical standards is in place for the pharmaceutical and medical device approval process, through the Food and Drug Administration's (FDA) inspection of the sites that conduct clinical trials, according to the agency's regulations for licensing of new drugs and devices and to the "Good Clinical Practice" standards of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
45. As a regulatory body, the FDA's human subjects regulations have sharper and more obvious teeth; for example, drug sponsors cannot use the results of research that did not adhere to the regulations in support of their applications for a license for a new drug.
46. It is important to note that such criticism has stimulated some beneficial change. For example, the revised Rule adds provisions that are apparently aimed at encouraging researchers to draft, and IRBs to demand, consent documents that will improve potential subjects' ability to understand what it means to enroll in a particular study. For example, in §__.116(a)(5)(i), the revised Common Rule states that the consent form must begin with "a concise and focused presentation" of "key information… organized and presented in a way that facilitates comprehension." It goes on to say that detailed information (from providing all the required elements of consent) must not be merely a "lists of isolated facts," but should be presented in a way that will facilitate subjects' understanding of "the reasons why one might or might not want to participate" §__.116(a)(5)(ii). Investigators — and perhaps even IRBs — may not feel enthusiastic about pursuing such a consent process, since for many clinical trials some subjects will be less inclined to enroll if they truly understand the likely benefits they will directly experience compared to those expected in an alternative therapeutic course.
47. Miller, *supra* note 36, at 90-91.
48. For example, one leading voice for research ethics has recently enthused over the "unprecedented opportunities to answer important clinical research questions…available through the analysis of massive amounts of data ("big" data) in commercial, health care, research, and government databases, in social media and mobile devices, and in growing collections of biologic specimens and clinical and genomic data." C. Grady, "The Changing Face of Informed Consent," *New England Journal of Medicine* 376, no. 9 (2017): 856-859, at 856.
49. H. Jonas, "Philosophical Reflections on Experimenting with Human Subjects," *Daedalus* 98, no. 2 (1969): 219-257, at 245.
50. *See, e.g.,* R. R. Faden, N. E. Kass, S. N. Goodman et al., "An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics," *Hastings Center Report* 43, no. S1 (2013): S16–S27; R. E. McKinney Jr., L. M. Beskow, D. E. Ford et al., "Use of Altered Informed Consent in Pragmatic Clinical Research," *Clinical Trials* 12, no. 5 (2015): 494-502.
51. Capron, *supra* note 3, at 5-6.
52. National Research Act of 1974, Pub. Law 93-348, July 12, 1974, Title II, Part B, §212(a).
53. The possibility is not a mere hypothetical, having been championed for example by Henry Beecher in the report he prepared for Harvard Medical School, when it wanted an alternative to the Nuremberg Code, which the Department of the Army had begun including in its contracts for research with human subjects around 1960. "The inescapable responsibility for determining what investigations may be done on a particular patient must rest with the investigator or physician concerned, bearing in mind that present-day specialization in medicine and complexity of procedures proposed or undertaken are frequenty beyond the grasp of the subjects involved." H. K. Beecher, "Tentative Statement Outlining the Philosophy and Ethical Principles Governing the Conduct of Research on Human Beings at the Harvard Medical School," (unpublished manuscript; undated) in J. Katz, *Experimentation with Human Beings* (New York: Russell Sage Foundation, 1972): 315, at 316.
54. C. Grady, L. Eckstein, B. Berkman et al., "Broad Consent for Research with Biological Samples: Workshop Conclusions," *American Journal of Bioethics* 15, no. 9 (2015): 34-42.
55. *See, e.g.*, D. Grande, N. Mitra, A. Shah, F. Wan, and D. A. Asch, "The Importance of Purpose: Moving beyond Consent in the Societal Use of Personal Health Information," *Annals of Internal Medicine* 161, no. 12 (2014): 855-862.
56. Yet, as Christine Grady has noted, "In survey after survey… people report that they prefer to be asked and given a choice about research even if there is little risk to them." Grady, *supra* note 48, at 857 (citations omitted).
57. President's Commission, *supra* note 17, at 108. A smaller majority of physicians hold the same view.
58. The preamble to the new Common Rule indicates that federal officials have taken notice of the public's cynical view about the purpose informed consent typically serves. In revising §__.116 to underline and beef up several general points about consent (by numbering them, instead of treating such considerations in a single, short introduction and then emphasizing the elements of consent by enumerating them separately), the drafters were sensitive to the complaint that long and complex consent forms serve mostly as "sales documents or means to protect against institutional liability." Department of Homeland Security et al., *supra* note 4, at 7212.
59. *See* note 22, *supra*, and accompanying text.
60. T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics, Seventh Edition* (New York: Oxford University Press, 2013): at 332.
61. A. M. Capron, "The Real Problem Is Consent for Treatment, Not Consent for Research," *American Journal of Bioethics* 13, no. 12 (2013): 27-29.
62. Beauchamp and Childress, *supra* note 60, at 332.
63. *See* note 11, *supra*, and accompanying text.
64. Jonas, *supra* note 49, at 239.
65. *See, e.g.*, K. A. Getz, "Charting a Course for the Patient Centricity Movement," *Clinical Researcher* 29, no. 2 (2015): 36-40; Patient-Centered Outcomes Research Institute, "Engagement" (2017), *available at* <https://www.pcori.org/engagement> (last visited Nov. 20, 2017).

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