

Part III:

DOCUMENTING THE INFORMED CONSENT EXPERIENCE

CHAPTER 7

Is Informed Consent in Reproductive Medicine in Critical Condition?

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.”

--Judge Benjamin Cardozo¹

Entities may do things only *with* consent, which must be solicited through another grueling barrages of disclosures. . . . Consider HIPAA's incessant disclosure requirements. My hospital distributes seven pages of disclosures in print so small I can't read them with my glasses on. One analysis placed these forms at a college reading level. . . . But what does the language matter, since no one reads the forms? One “covered entity” told me that in three years I was the second patient to ask for a copy of his HIPAA disclosure form.

--Carl Schneider²

These days, it's easy to overlook the human elements within the informed consent project, to forget it's a product of relationships and not just a litigious culture, and a process of communication, and not merely bureaucracy. As Judge Cardozo's idealistic portrait of informed consent suggests, its importance hinges on many factors that promote patients' and providers' wellbeing, and protect their relationship—including safeguarding autonomy, dignity, and decision making. Yet, these lofty goals can be undermined by informed consent's “dark side,” to which

Schneider alludes, the idea that consent is little more than a bureaucratic ritual, designed to protect doctors and medical facilities at patients' expense. Informed-consent-as-relationship can disappear in the no-man's-land between the right to choose medical treatment and how that choice is carried out. Consent in IVF takes place against conventional expectations that posit that consent forms are incomprehensible and protect doctors at patients' expense, and that patients don't read or care about them. Are these expectations accurate for patients undergoing IVF? And, regardless, how do they affect patients' and providers' informed consent experiences?

Answering this question requires interrogating how patients and providers (including physicians, nurses, and mental health professionals) define and experience both informed-consent-as-ritual and informed-consent-as-relationship, dissecting it into its constituent parts of documents (rituals) and conversations (relationships). Informed-consent-as-ritual is conventionally thought to be problematic. The consent project in reproductive medicine brings unique challenges; forms are longer, and choices present different ethical and moral questions. Moreover, most patients don't experience informed consent as conventional assumptions suggest, but believe that it begins before forms are signed, and is influenced by treatment relationships, and many consider themselves well-informed beforehand. Having mapped the larger relationships in which informed consent takes place, it's now possible to turn to the informed consent project itself.

This informed consent project can be understood as both a bureaucratic practice (discussed in this chapter) and as an experience (discussed in Chapter 8). Both perspectives are critical. On the one hand, bureaucratic institutions like law and medicine determine what informed-consent-as-ritual must achieve and how, creating particular consent practices to meet these goals. On the other hand, experience clarifies how formal bureaucracy and informal relationships influence one another. Understanding how informed consent rituals and relationships work together helps us to identify

more realistic consent goals, assess why current consent practices hamper these objectives, and design practices that are more responsive.

Is Informed Consent Informed?

Informed consent to medical treatment (as ritual) is a legal and ethical imperative, connected to the four moral principles of medical ethics: autonomy (respect for persons), beneficence (do good), nonmaleficence (“first, do not harm”), and justice (be fair).³ These same principles also apply to healthy interpersonal relationships, where participants respect and look out for one another. But somehow, they’ve become lost in translation from theory into practice. While legal and medical experts have emphasized “informed-consent-as disclosure”⁴ of material information, this focus overlooks the patients’ understanding and autonomous choice. An inclusive definition of informed-consent-as-ritual, in contrast, includes several other dimensions: *threshold* elements (patients’ ability to understand, competency to decide, and ability to make a voluntary decision); *information* elements (disclosing material information, recommending a plan, and patient understanding); and *consent* elements (outlining a treatment plan and giving authorization).⁵ This definition accommodates the complementary roles of patient and physician, as well as the many behaviors, technologies, and stages the informed consent project involves.

The all-weather, tried-and-true definition of informed consent (here, informed-consent-as-ritual) requires providers to disclose information material to treatment decision making, like risks, benefits, side effects, and alternatives,⁶ as well as providers’ treatment recommendations, and consent’s nature and limits.⁷ Within this definition, legal standards differ; for example, physicians might have to disclose what the *reasonable physician* would disclose, or what the *reasonable patient* would want to know. If patients’ health circumstances allow, these disclosures typically occur in consent

forms and conversations, where patients can ask questions before signing. But patients can have trouble understanding medical documents and consent forms, including technical or legal jargon.⁸ The average consent form is 12 pages long,⁹ tempting them to skim through rather than read carefully. Moreover, more information isn't always better;¹⁰ patients might give consent documents short shrift if they think that forms legally protect providers, and might be in the habit of signing forms in doctors' offices quickly, without reviewing them. Thus, there is great tension between the sad reality of what informed-consent-as-ritual often is (or is conventionally expected to be) and the idealistic conception of what it could and should become. These tensions are palpable even within something as basic as professionals' definitions of informed consent (as ritual).

Reforming Informed Consent

Many professionals practice reproductive medicine because they enjoy helping patients to build longed-for families. But the same potentials that make this field attractive to professionals also expose it to criticisms that practitioners are playing God and taking advantage of desperate patients:

It's just the stigma about childbirth. . . . It's a billion-dollar-a-year industry. [The assumption is that] people are out there to rip you off. You've got a vulnerable population, so [critics assume that we're thinking that] the way to resolve that's just to give them so much information that they don't even know what to do with it. I think that's behind a lot of it. It just gets a lot of scrutiny. (Lab Director Keane Schultze)

In patients' and professionals' comments, their opinions and preferences about informed-consent-as-ritual align; both strongly prefer effective interpersonal partnerships and honest and transparent communication. Both also tend to view signing consent forms as a bureaucratic ritual. For most, an ideal consent interaction unfolds like Natalia Payne's visit:

with [the] first doctor that we love, when we went in for our consultation on IVF, it was in a conference room. When they talked about things, they had slides and brochures to go with every single page so we understood, they actually discussed with us and let us ask questions and read the whole document before we signed, and we [] did that with about seven different consents.

In IVF, informed-consent-as-ritual mixes formal and informal elements, relying extensively on lengthy (and bureaucratic) documents and interpersonal provider conversations. Patients and professionals know that these conversations are integral to the informed consent project, that they function differently than documents, and often prefer conversations to forms outright. But conversations have a critical legal shortcoming: unless they're recorded, they're undocumentable, and provide poor evidence of what occurs. This creates an impasse. Patients recognize they're emotionally, physically, and financially vulnerable, but most believe the best protection lies in healthy relationships with trusted physicians, not in consent forms. But while these treatment relationships are enormously effective in *preventing* adverse outcomes, they carry little credibility within law and medical administration, the rule-based institutions that create, mandate, and monitor consent practices. And outside of these institutions, consent forms have little weight *because* they are seen as bureaucratic, and even inspire cynicism. This, then, is the question: how do patients and

professionals negotiate and experience informed-consent-as-ritual using both interpersonal communication and bureaucratic documents, given each tool's advantages and disadvantages?

Answering this query requires assessing how bureaucracy shapes the informed consent project. The term "bureaucracy" connotes a formal system that prioritizes rules and rationality, with time-consuming and document-intensive routines and policies. Bureaucracies rely on formalism, or excessive adherence to prescribed principles. Extremely bureaucratic organizations are impersonal, unemotional, detached, and rigid, mechanistically based on fixed, absolutist roles, routines, and rules. But in the "real world," formalism is in tension with its opposite, informality, which is personal, emotional, and flexible. Because relationships and interpersonal communication have informal qualities, they threaten to disrupt and undermine bureaucratic institutions.¹¹ In practice, most patients dislike bureaucratic medical care, and view the "fertility factory" as nightmarish. Instead, they seek treatment in clinics that offer individualized, flexible care through partnerships with emotionally sensitive providers.

Informed-consent-as-ritual is conventionally seen as a formal process, where professionals ensure their patients review and sign consent forms before treatment. Medical bureaucracies tout informed-consent-as-ritual's educational benefits and legal protections at the same time as they support strong doctor-patient relationships (informed-consent-as-relationship), but realistically they treat these ends as distinct and largely unrelated. And signatures are different from authentic patient understanding; as Simone Henry noted: "I'm not convinced that that paperwork really showed that I was a well-informed patient, so to me, that's . . . where it becomes [focused on] legality."

But in practice, informed-consent-as-ritual is not entirely formal; its most important goals are at least partially informal in nature, or accomplished through partially informal ends, including educating patients, obtaining consent, coordinating clinic practices, and establishing procedures that safeguard patients from doctors, and doctors from lawsuits. These tasks all require human

relationships, not merely paperwork. Informed-consent-as-ritual's informal qualities are even more apparent in its more subtle accomplishments. Informed-consent-as-ritual defines and reinforces doctors' and patients' hierarchical roles in treatment relationships, confirming structures of power and authority. It informs patients that bad things sometimes happen, and tells them where and how to seek redress afterwards. Informality makes this news more palatable, and less threatening. Simply put, informality is more comfortable. Patients want to know they're protected if something bad happens, but they don't want to be continuously reminded that formality or bad outcomes exist, and dislike being confronted by reminders at odd times, like when they're entering an informal doctor-patient relationship.

These tensions between formality and informality explain why patients might feel that informed-consent-as-ritual does a poor job of educating them, and protects doctors at patients' expense. Consent forms, after all, are like other papers that people often disregard before signing, like HIPAA forms or mortgage documents. Patients might not regard conventional consent rituals as very important: they trust their providers; think nothing bad will happen, or find consent forms too time-consuming, technical, lengthy, and overwhelming. Informed-consent-as-relationship starts to break down when informed-consent-as-ritual is the butt of patients' and providers' suspicion, skepticism, cynicism, and humor, further decreasing consent forms' authority and perceived usefulness. Bureaucrats argue that these breakdowns can destabilize the informed consent project's legal protections, exposing doctors and clinics to lawsuits. After all, bureaucratic processes only work if users believe that they can effectively advance well-being and protect patients. If bureaucratic processes can't accomplish these ends, then users will pursue their goals through informal communal relations, further undermining formality and bureaucratic organizations' authority.

Indeed, patients do try to circumvent informed-consent-as-ritual as their respect decreases (especially forms), inadvertently depriving themselves of important (albeit bureaucratic) protections that require compliance to work. If patients circumvent consent forms by not reading them, they'll likely lose malpractice claims in court because judges will presume that patients read the documents they signed, and should be held to their terms. Patients don't intend this result; they think they're merely opting out of an ineffective routine, instead relying on treatment relationships and communication, and don't think they'll ever end up in court. Meanwhile, health bureaucrats who create and administer consent aids know that patients might circumvent consent procedures, and use several strategies to discourage this behavior, like shortening and simplifying forms. Conventional strategies double down on formalism, making consent forms longer and more technical, emphasizing documentation, and discouraging conversations. Only recently have they begun to adopt new techniques, like shortening and simplifying forms.

But these conventional, overformalistic strategies don't increase compliance; they diminish it. The more forms with which patients are confronted, and the more thorough these forms become, the less likely patients are to read and engage with them. From the formal, bureaucratic perspective, *this* noncompliance seems even less reasonable, under the logic that people can't rationally ignore forms that are so lengthy, informative, and clearly important to their well-being. From patients' perspective, however, it makes perfect sense. Why would anyone waste their time on consent documents that are incomprehensible, misallocate priorities, and fail to protect patients—the most vulnerable parties, with the most to lose and the least power? Moreover, overformalism brings bureaucrats into patients' lives in ever more intrusive ways, transforming the provider-patient dyad into a reproductive rumpus. Fertility care thus comes to resemble other contentious practice areas like abortion care, where bureaucrats have already staked out a permanent presence. And without

patient buy-in, informed-consent-as-ritual, and thus the informed consent project, become ever weaker and ineffective.

Finally, overformalist tactics like longer, more technical consent forms also change treatment relationships, distancing doctors from patients, reinforcing professional detachment, and strengthening traditional power structures. Certain levels of interpersonal distance are appropriate and productive in medical treatment, but distance becomes dangerous when it encourages providers to view patients as diagnoses rather than as people: the endometriosis case in Room 2, the ectopic pregnancy in Room 3. With professional detachment comes a renewed commitment to technical aspects of care, which traditionally stress pathology and physiological needs, not illness's social and personal dimensions.¹² This is the last thing patients want; such distance threatens those qualities patients prioritize most in fertility care experiences.

Thus, put simply, when patients think that consent offers weak protections and misguided priorities and try to opt out, their attempts to circumvent consent processes can trigger more formalist tactics that only reinforce patient cynicism and contravention. Ultimately, this vicious cycle erodes public trust in existing rules, processes, and institutions, weakening their legitimacy and authority.¹³

Thus, innovation, not overformalism, is the best response to patient circumvention—why not change those elements of informed-consent-as-ritual that don't seem to work, potentially by swapping documentation for new consent technologies, like multimedia or e-learning applications?¹⁴ While overconformity's pressures can stifle creativity and innovation, they can also serve as a crucible, forging new improvements to the informed consent project.¹⁵

Patients' and providers' reflections on whether consent forms are important or bureaucratic and whom they protect illustrate the advantages and disadvantages of formality and informality. These comments explore the social, cultural, and institutional contexts in which informed-consent-

as-ritual takes place, and how these settings influence participants' experiences, for better and for worse. The formality of certain consent routines—especially signing documents that may appear voluminous, authoritative, and legalistic—inspires gravitas, while the informality of other consent practices—like consent conversations tailored to specific questions and needs—provides individualized support and information. The most promising consent improvements incorporate aspects of both.

(Non)Working Agreements: Patients' Thoughts on Informed Consent's Importance

Patients have nuanced opinions on whether they consider informed-consent-as-ritual to be important, on the one hand, or bureaucratic and redundant, on the other. Half deemed consent important because it educated them about IVF procedures and medications. Many felt consent fit within both categories; 38% noted that it seemed less relevant when they didn't anticipate problems in treatment cycles or relationships. Only 12% of patients judged consent processes to be entirely bureaucratic or redundant. These reflections are complemented by surveyed patients' divided opinions on whether they felt the consent ritual was something to "get out of the way" and whether they took consent forms seriously. While 95% took forms seriously, 45% said they were something to get out of the way, implying that some patients didn't spend much time with the consent process.

To many, informed-consent-as-ritual is bureaucratic because it's synonymous with paperwork. "It feels so bureaucratic, because you do it at every doctor you go to; you have your HIPAA consent," noted Marta Lyons. The trope of informed-consent-as-bureaucratic-ritual goes hand-in-hand with the idea that patients sign consent forms without reading them. After all, if "no one really reads them and no one really takes them seriously" (Anne Kelley), why should patients invest more effort than a signature? Cecelia McBride alleged that the entire informed consent

project is flawed: “I think the people who actually acquire the signatures usually don’t do a good job of explaining the significance of informed consent. . . . I don’t think informed consent is very valid in most cases.” But others, like Nicole Bell, suggested that other (informal) measures fill gaps in understanding: “[the forms are] very wordy; most people aren’t sitting down reading all of them. But the nurses . . . summarized [them].” This implies that formalist consent forms by themselves are inadequate.

Most patients regard consent forms as important and useful. Cautioned Lena Coleman, “you’ve got to sign a contract of some sort; you’ve got to . . . say that you understand what’s going on.” Jenna Moreno found it educational: “I do think they’re important, because there were a lot of questions that I hadn’t considered. . . . There were things that my husband and I had to sit down and talk about because I didn’t know.” And forms ensure everyone’s literally on the same page, moving forward with a common understanding. “I think the patient should [] be reminded of what they’re getting into, reminded of what they’re responsible for, and what the doctor’s responsible for, and to be aware of what the risks are,” asserted Kelley Bates.

Informed-consent-as-ritual might be more important for some medical procedures than others: “[for] giving blood or getting a flu shot [informed consent] is more of a bureaucratic, redundant thing. . . versus elective surgery, where they’re going to sit you down and talk you through everything” (Christopher Franklin). And informed-consent-as-ritual often seems more relevant in reproductive medicine than other medical contexts. “Outside of infertility, I would say they’re redundant and bureaucratic because they’re always ‘You could die from this procedure’ type of forms. But with IVF, I think they actually were informative,” Danielle Greene clarified. “It really did say, ‘Ok, here’s the possibilities of twins and triplets and more. And think about selective reduction. Think about what you’re going to do with the embryos that you don’t use.’”

Several patients describe informed-consent-as-ritual as both redundant and important. “I think the bureaucracy part is they’re very wordy. But certainly it’s important that everybody understands that the patient understands,” observed Nicole Bell. While Ethan Reeves believed “the forms themselves are kind of redundant and bureaucratic,” he felt “the discussions that they prompt are very important.” Some patients noted consent precautions were theoretically important, but personally irrelevant. They believed all would go well: “To me, they’re bureaucratic because we don’t need them, . . . but if things took a turn and lawyers got involved or something, I’m sure things will come back up, but now, I don’t see significance in the paperwork” (Rodney Hughes).

Patients often take informed-consent-as-ritual only as seriously as their providers do; professionals’ approach to the consent process and how much time they invest in it matter enormously, as 29% (interview) of patients observed. Shannon Ward complained her physician didn’t emphasize consent forms enough, because there was no informal discussion of consent information:

If we had had a better relationship with our doctor, I would’ve been able to make a significantly more informed consent. His attitude was like, “It’s all there on that paper.” . . . I felt incredibly informed about the process in general, but not to my specific case.

Having been a patient at two different clinics, Simone Henry observed many differences in how each conducted informed-consent-as-ritual; her first clinic “had such a casual attitude: ‘Ok, this is just paperwork, you have to sign.’” But consent seemed much more important at Simone’s second clinic, largely because of consent interactions:

they read everything to you and they go over it, but you wind up having more of a conversation, and it changes the relationship. It's not, "Here is something that you need to sign before you can see the doctor"; it becomes almost, "Okay, we're going to go through this together."

Informed-consent-as-ritual also seems more consequential when patients feel they can realistically decline treatment, or when forms require them to choose among several options. Anne Kelley felt consent forms' value could vary: "I think . . . when they actually contain decisions . . . they're very important, . . . but if they're just like, 'Hey take this drug; here's the multiple side effects and you could die,' no one really reads them and no one really takes them seriously." Then again, at this time, patients' minds may be preoccupied with IVF's benefits—conceiving—and not its risks, and certainly not on its alternatives: "you're going there to get pregnant, and it's all about having a baby. . . . That's a sidestep; . . . it's like a game show; you're to the end, and you're almost about to win. The rest of it's secondary" (Luke Holloway). Related Deanna Douglas, "I think I'm just too wrapped up with my own . . . emotions to think about what paperwork I signed."

No doubt the timing of informed-consent-as-ritual—of necessity, before treatment—also matters, because patients aren't yet far enough along to know why such protections might be necessary. Cynthia Gardner recalled, "I didn't think I needed to be protected in most cases." Before treatment, forms seem to disproportionately benefit doctors. Patients' perspectives are also influenced by their good health; they are generally young, and unlikely to have experienced serious health complications or medical errors. And chances are, even if a problem occurs, it won't result in liability; such medical errors rarely produce lawsuits in fertility care.

Moreover, patients' remarks suggest that formalism does lead to patient noncompliance, but not for the reasons critics suggest. Because patients resent the bureaucratic and litigious cultures

that they believe necessitate informed-consent-as-ritual, they take documents less seriously, and are more likely to dismiss the real risks these forms describe. Consent violations and malpractice seem a problem that *others* experience when exploited by *other* providers. Few patients think that *their* physician could perpetrate such acts. “Unfortunately, there are some not-[so]-good people in the world,” Christine Zimmerman opined, “and I think that lawsuits are for people that feel like they didn’t have informed consent.” Some patients resent that *they* have to endure such tedious routines, but make the best of it nonetheless. “I just wish we didn’t live in such a culture where the doctors are so afraid of being sued that they have to explain every slightly possible bad outcome in a consent form,” related Jackie Carson. “But since we do, I think they’re very important. If I were a doctor, my consent forms would have every single thing that could possibly go wrong in them.” Thus, many patients regard informed-consent-as-ritual as a byproduct of a culture of civil liability in which doctors are its victims, not its violators.

Doctored Information: Perceptions of Informed Consent Protections

Perhaps the more nuanced (and perhaps more cynical) question wasn’t *whether* informed-consent-as-ritual was important, but *for whom*—essentially, whether patients felt protected by formalist consent processes. Patients were almost equally divided on whether consent forms protected doctors (40%) or patients (47%). The remaining 13% of patients thought informed-consent-as-ritual protected both parties.

Patients regard the signed documents as shields doctors can raise for protection against a civil suit: “they’re afraid of getting sued, and so they need something to say, ‘No we told him the risks, and he signed off on them.’” (Andre Baker). Brooklyn Knowles was more blunt: “it seems like a CYA [cover your ass] thing on the medical profession’s part.” Luis Torres believed forms

protected doctors, because doctors created them and distributed them to patients: “otherwise I [as the patient] would be having them sign something if I was trying to protect myself more.” But this doesn’t make informed-consent-as-ritual worthless; it might have a different type of value. As Deanna Douglas asserted, “I guess it’s helpful in the sense of just knowing what you’re getting into. . . . It still made me feel better, I guess, that he’s still legally obligated to do something for me, since I’m giving him all this money.” This is a more transactional view of consent and the treatment relationship—as a contract, triggered by payment of a fee.

Those who think doctors receive the lion’s share of protections from consent forms also observe that consent forms’ legalistic structure and fixed provisions favor providers and clinics. The legal terms of Racquel Kennedy’s consent forms struck her as inequitable: “I didn’t really like the part about where you’re . . . releasing [the clinic] from damages if they do something wrong. . . . If we get eight eggs and we have extra embryos and they drop them on the floor, then that’s nobody’s fault.” One-sided terms left patients like Rodney Hughes feeling unprotected: “if something serious were to happen, something huge error, I don’t feel that we’d . . . win.”

Similarly, Patients’ lack of control over consent document provisions—together with formalist rigidity—also suggests that forms disproportionately protect providers: “I think it’s there to protect the doctor, because it’s not like you can write in your own little clause” (Rosa Grant). Christopher Franklin observed that some didn’t allow patients to make changes: “any time that you’re not given an option to change . . . or negotiate the terms and conditions, obviously it’s meant to protect the person that’s handed you the paper.” He noted many patients may feel uncomfortable suggesting changes, but wished more would:

I think a lot of people don’t understand that they can negotiate terms and conditions . . . and this situation is, in most senses, a business arrangement. . . .

You don't want to create waves . . . [and] they probably don't get that question [about changing the forms] a lot. . . . You absolutely, I think, are within your rights to go back to him, [saying] "There's something I'm not comfortable with, and I'd like to strike this." And then that office can always say, "Forget it, there's the door." If they're showing you the door, then that paperwork's meant to protect them.

But if patients think the only way they're permitted to engage with forms is to sign them, there is little incentive for them to take more initiative. To these ends, a few said consent processes would be more meaningful if they required patients to exercise more responsibility: "I think in most cases it ends up being more protective for the doctor, just because patients treat it so lightly" (Cecelia McBride).

A smaller group of patients felt that forms protected both doctors and patients. Sergei Bennett, an attorney, believed consent protections might have a larger impact on patients, most of whom wouldn't otherwise consider adverse outcomes: "I know most people don't think about what happens if you get divorced and have a frozen embryo somewhere, but I know the legal implications of that and how critical it is. So it's very important to have all of that decided up front." Sara Harper believed its protections were slanted in providers' favor: "I think that in some ways it's biased, because they're trying to avoid malpractice. And I think that it is also important to know what the risks are going in."

Ultimately, these reflections on informed-consent-as-ritual confirm that, when patients believe consent is largely a bureaucratic ritual that benefits providers, they don't think it's effective. Consequentially, patients pay less attention to consent procedures and seek more informed protections in treatment relationships. "It's about being sued, and so that's why, when I view it that

way, I'm not paying attention as much," Marta Lyons explained, "So I didn't feel like it was as much of the medical process, which it should've been." This, then, is one of the informed consent project's greatest ironies—a procedure meant to protect patients ends up making them feel more vulnerable, either because the consent form terms seem biased towards professionals, or because no lawyers would take such a case, as Anne Kelley discovered. Since her uterus was half-size, Anne's consent forms stated that only *one* embryo could be transferred. But her provider transferred *three*, giving her triplets:

[Informed consent] didn't do much for me. It didn't protect me. I still ended up with the triplets and absolutely no basis to have any retribution or whatever the right word is for that. . . . I definitely did consult a lawyer because I just needed to for my own psyche, because I needed to know what my options were. And they basically said, "You have none because there's no guarantee that you could carry a pregnancy to term anyway"—and that was before I did. . . . I was like, "No, there's an informed consent [form] there [that] spelled out O-N-E, one embryo should be transferred." . . . We were told, "Oh sorry, you can't pursue any justice based on informed consent." . . . Why did I sign that then?

Patients may be surprised to learn that many professionals also hold consent forms in low esteem, and believe they disproportionately protect providers. If anything, professionals are *more* likely than patients to regard consent forms as legalities: "I think the documents that they sign are important from a legal point of view. Nothing you really tell them really stands up in court unless you've got written documentation" (Dr. Gerard Gabler). This diminishes consent forms' perceived importance within care relationships. Documents may even seem like "more of a formality" (First

Year RE Fellow Dr. Yazmin Kuhn); Dr. Nicole Potter opined that forms are “somewhat meaningless,” and Dr. Don West observed the “written part is to cover your back, unfortunately.” Some professionals even question whether consent forms effectively accomplish these legal aims: “I’m not an attorney, but from what I understand, it really doesn’t matter if they sign it or not” (Dr. Don West). And several doubt whether consent forms can simultaneously deter malpractice *and* educate patients. These contrasting purposes—education and protection—capture two clashing images of the provider-patient relationship—an interactive, trusting treatment relationship versus one that is suspicious, adversarial, and legal. The question is, which one is the most authentic?

Conclusion: The Formalism in the Fine Print

For these reasons, informed-consent-as-ritual is at something of an impasse. As patients react to overly formalistic consent reforms like longer and more thorough documents with avoidance and cynicism, the continual tug-of-war between formality and informality threatens the entire project. We may laugh at informed consent bureaucratic banalities, but this laughter is a symptom of despair, a warning sign that we regard these problems as intractable within medical practice.

But both formal and informal processes are necessary for the informed consent project to work. Formalism is the reason we have consent procedures and routines in the first place; informality explains why consent can be an especially effective patient protection. Bureaucratic, formalistic elements may often inspire cynicism and a lackadaisical attitude, but they ensure that such consent procedures are followed, and the consistency of consent routines might prompt patients to fully engage in the consent process and have confidence in its protections. Meanwhile, in other contexts, informality might make providers seem unprofessional and undercut their authority;

but here, informal, interpersonal dimensions can encourage trust between patient and provider, and encourage providers to tailor generic consent forms to patients' individual needs.

The adoption of patient-centered care—in effect, a sustained focus on informed-consent-as-relationship—stands to become a new, larger battleground in the war between formality and informality. In the past two decades, medical standards have grown to encompass a patient-centered philosophy, the conscious adoption of the patient's perspective.¹⁶ Patient-centered care respects patients' values, preferences, and expressed needs; attempts to coordinate and integrate different types of medical care; provides information, communication and education; prioritizes patients' physical comfort; provides emotional support and alleviates fear and anxiety; involves family and friends in care processes, and ensures continuity of care when patients leave clinical care settings.¹⁷ Focused on compassion and empathy, patient-centered care keeps bedside manner, communication, and doctor-patient relationships at the heart of the care experience. It represents a formalization of the informality that patients seek, in a sense using informality to preserve and secure formalist systems, while providing the compassion that enhances credibility. Such bureaucracies can seem empathic rather than cold, and recognize how treatment relationships are as critical to informed consent as its rituals.

But many patient-centered care principles are at odds with older formalist conventions; for instance, long, technical, consent forms brimming with jargon are the opposite of shorter, easier to read aids. But because patient-centered care is a comprehensive *model* of patient care, not merely a reform affecting one aspect like informed-consent-as-ritual, it might be strong enough to compel a new formality, one very different from older, repudiated care models like paternalism. A new patient-centered formalism could effectively wage a slash-and-burn campaign against cumbersome arrangements of authority and bureaucratic busyness; this new formality could prioritize patient education and understanding while continuing to build in effective provider protections.

For now, however, having a basic understanding of formality, informality, and the tensions between them makes it possible to assess how they interact in practice, and in particular with different types of consent forms: those describing IVF protocols and those recording patients' embryo disposition decisions.

¹ *Schloendorff v. Soc. of NY Hosp.*, 105 N2d 92, 93 (NY 1914) (overruled on other grounds by *Bing v. Thinig*, 143 N.E.2d 3, 7-8 (NY 1957)).

² Carl Schneider, *HIPAA-crazy*, HASTINGS CENTER REP. 36(1) 10, 11 (Jan.-Feb. 2006).

³ TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 79, 81 (5th ed. 2001)

⁴ *Id.*

⁵ *Id.*

⁶ See Nancy E. Kass, et al., *An Intervention to Improve Cancer Patients' Understanding of Early-Phase Clinical Trials*, IRB ETHICS & HUM. RES. 31(3): 1 (2009).

⁷ *Id.*

⁸ See Gordon Willis, *Cognitive Interviewing as a Tool to Improve the Informed Consent Process*, J. OF EMPIRICAL RES. ON HUM. RES. ETHICS 1(1): 9, 9 (2006).

⁹ See *Id.*

¹⁰ See Yarl Schenker & Alan Meisel, *Informed Consent in Clinical Care: Practical Considerations in the Effort to Achieve Ethical Goals*, JAMA 305(11): 1130, 1130 (2011).

¹¹ RUPERT HODDER, EMOTIONAL BUREAUCRACY 6, 10 (2011).

¹² MARGARET GERTEIS ET AL., THROUGH THE PATIENT'S EYES: UNDERSTANDING AND PROMOTING PATIENT-CENTERED CARE 281 (2002).

¹³ HODDER, *supra* note 11, at 181.

¹⁴ See generally Jody Lyneé Madeira & Barbara Andraka-Christou, *Paper Trails, Trailing Behind: Improving Informed Consent to IVF Through Multimedia Applications*, J. L. & the Biosciences 2-38 (Jan. 18, 2016).

¹⁵ HODDER, *supra* note 11, at 181.

¹⁶ Gerteis et al., *supra* note 12, at 5.

¹⁷ *Id.* at 5-11.