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Behind Closed Doors
IRBs and the Making of Ethical Research

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INTRODUCTION

Behind Closed Doors

Governing with Experts

In 1961 the town of Bethesda, Maryland, was—as it is today—a quiet, affluent suburb of Washington, D.C. Thus, it may have seemed improbable to residents that two federal prisoners awoke near the golf course on January 6 of that year and left town in time to catch a midmorning flight out of the Washington airport.¹

The prisoners had been neighbors of a sort. That winter, the two men lived in Bethesda just off Wisconsin Avenue at the National Institutes of Health (NIH) research hospital, called the Clinical Center. Throughout the 1960s, the federal government moved men from penitentiaries across the country to the Clinical Center for several weeks or months at a time, most often in groups of twenty-five. They stayed in wards set aside for the study of infectious diseases and pulled off only a few “unauthorized leaves,” the phrase that NIH leaders used to refer to events that were more colloquially known as escapes.² Throughout the 1960s, NIH researchers infected them either with malaria or with viral diseases; pneumonia, flu, or an illness caused by simian virus-40. Research on prisoners was common in the United States at the time, and American scientists worked hard to craft domestic and international ethics standards—the 1964 Declaration of Helsinki, for example—that allowed them to continue prisoner research.³ Although commonly done and formally allowed, prisoner research was still contentious. Sensing this, NIH leaders made sure the prisoner program remained “little known to the general public,” as the surgeon general phrased it in 1964. Even within the Clinical Center, it struck some NIH doctors, lawyers, and administrators as somehow wrong to infect and study prisoners. But despite their misgivings, they went along with research practices that worried them.
Lawyers who were personally uneasy nonetheless endorsed the research in their professional role as legal counsel to the U.S. government. Likewise, doctors who felt troubled made peace, eventually, with their colleagues’ practices.

At NIH in the postwar decades, research that might have prompted controversy quietly proceeded because the leaders of the Clinical Center had collectively agreed on a method for recognizing a good, fair decision about whether research was acceptable. If a study was endorsed by a particular group of scientists, called the Clinical Research Committee, the study became acceptable. The committee, in effect, defined whether studies were proper. This was procedure, and—in the case of the prisoners’ study and in thousands of studies since—research went ahead because procedure had been followed. In this case, like many others, ethics rules served to enable research as much as to restrict it.4

This book explores how researchers designed U.S. government rules for the treatment of human subjects after World War II, and it examines the present-day consequences of their choice to adopt review procedures rather than ethics principles. NIH leaders built and defended rules that they felt suited their particular circumstances. In so doing they invented a new federal standard for how courts, colleagues, and research participants would learn to recognize ethical research. In the decades since the Clinical Center opened in 1953, there have been profound changes in the scope, funding, and ethics of research on human subjects. But what has endured is a way of making research ethical, a method of “governing with experts.” In the name of federal law, groups of individuals thought to have unique qualifications approve (or reject) researchers’ choices about who should participate and how participants should be studied. In the process, they also shape research because they are empowered by law to require changes to studies before they approve them. More often than not, expert groups do exercise their legal authority to request modifications. Whether that involves editing the questions researchers ask in a survey or trimming the number of patients that doctors enroll in a clinical trial, review boards help to create today’s biomedical and social science research.5

NIH doctors, lawyers, and administrators adopted this method of governing with experts to manage research inside the NIH Clinical Center in the years when words like Sputnik, double helix, and McCarthyism entered common parlance. They did not anticipate at the time that their particular local arrangement would endure. Yet it became the model for human-subjects review boards, and its legacy is with us today wherever scientists and scholars plan to study human beings.
Rule Experts and Knowledge Experts

Part of the role of government agencies is to empower people to make decisions on behalf of the people being governed. Whereas some laws are in place to keep order among citizens, another set of rules—administrative law—guides the daily work of government employees. The point of the rules is to enable civil servants to make rote, seemingly impersonal decisions in our stead. In theory, the rules are so precise that they would allow all qualified people to reach the same conclusion. Administrative laws are designed to make human decisions appear to be objective and beyond the judgment of a given individual.

This imperative of objectivity surrounds us. Think of food inspectors, drug regulators, and housing authorities. Imagine the mindless rule-follower conjured by the cliché that decisions are made by “some bureaucrat in Washington.” The rules that civil servants apply are often quantified: calorie counts, chemical ratios, and rating scores, for example. The paradox is that qualities of human experience that would not otherwise be thought of numerically—the seeming intangibles and passions of learning, loving, and living in general—are often quantified when inserted into regulatory apparatuses so that rules can be applied. Civil servants become agile in using a narrow set of regulations, and gradually, in the course of doing their jobs, they become rule experts.

Most citizens are limited not only by time but also by the knowledge needed to make informed collective decisions. None of us know all of the things needed to participate meaningfully in each decision that affects us, and, frankly, neither do civil servants. For this work, governments turn to knowledge experts.

Government agencies outsource decision making to people who are already trained in specialist areas. Groups of experts in science, law, medicine, and other fields of formal knowledge have been tapped to do the everyday work of applying administrative laws to concrete cases. During the 1960s, the U.S. Congress passed an unprecedented number of federal statutes that dramatically expanded the scope of federal programs, and these programs were overwhelmingly aimed at regulating the natural environment and human health. As a result, specialists in these fields have been incorporated in growing numbers into the process of writing and applying regulations. Academics, for example, decide which medicines are safe to study and prescribe, how much doctors get paid through Medicaid, and which artists, scholars, scientists, and businesses are worth supporting with public money.
These people are what anthropologist Donald Brenneis calls “nonce bureaucrats.” They are bureaucrats only temporarily and for a specific decision-making purpose. Their full-time jobs are elsewhere, often doing whatever it is that makes them knowledge experts in the first place, such as practicing law, researching chemical compounds, or studying scripture. They are called on to make decisions that defy strict, quantifiable rules—decisions that call instead for judgment.

Administrative laws empower knowledge experts to make seemingly idiosyncratic decisions. For rule experts, use of discretion would be an abuse of power; but for knowledge experts it is their mandate. Legal scholar Duncan Kennedy argues that discretion has been built into rational—that is to say, rule-bound—decision-making practices in modern democratic governments. In many cases, making value judgments is not antithetical to following the official rules but is precisely what it means to follow the letter of the law. The value of nonce bureaucrats to governments is their apparent ability to use discretion soundly, not to avoid discretion altogether.

**Declarative Bodies**

But knowledge experts create a problem of their own. If democratic decisions are supposed to be beyond the caprice of an individual, how can we be sure that an expert uses her discretion to arrive at an objective (read *fair and democratic*) decision? The answer is that legitimate discretionary decisions have to be made by a group: a body of multiple experts. Citizens, of course, have to abide by these choices, which are often made in seclusion in settings that, if not formally restricted to the public, are at least cumbersome to access. And while we may protest, resist, or appeal their group decisions, doing so would work against the grain of the status quo, which these bodies have the authority to set.

That is to say, their words matter. Administrative law gives certain people the authority, in specific contexts, to change our shared reality. The classic example of how some people’s words have special power is that of a justice of the peace saying “I now pronounce you legally married.” He is not describing a married couple; rather, he is creating one. For these words to stick—that is, for other people to treat the pair as a married couple, both legally and socially—the setting has to be appropriate (e.g., spoken when all three are present), and everyone else has to agree that the authority figure has the power he claims (i.e., that he can marry people). Then, as if by magic, people’s financial, legal, and social worlds can change.
It is the same with the entities I call *declarative bodies.*\textsuperscript{16} I use this term to demarcate groups of knowledge experts who are empowered by law to make decisions for citizens. The say-so of these declarative bodies has tangible, material consequences. For example, the Federal Reserve Board decided which institutions American taxpayers would keep afloat in the 2008 financial crisis, and the Medicare Payment Advisory Commission tells doctors how much they will get paid for seeing low-income patients. The decisions of these expert groups are just words, and yet those words have the power to change the world in which we live.

One type of declarative body decides whether research on people can proceed. These groups are called institutional review boards (IRBs), and their archetype was the Clinical Research Committee developed at NIH. Today, an IRB is supposed to sign off on any study that uses “human subjects” before it can take place, whether the researcher plans to observe participants in a community meeting or to test a new drug on children. IRBs decide who may and may not be studied and what may and may not be done to people in various circumstances. IRBs are declarative bodies because they are empowered to turn a hypothetical situation (this study *may be* acceptable) into shared reality (this study *is* acceptable). It is a testament to the power of their words that IRBs rarely disapprove studies but regularly change them. In so doing they change what is knowable.

**IRBs in Practice**

Almost all hospitals, universities, and other organizations that support research on people have IRBs, including private companies and government agencies. Today, the federal government counts nearly four thousand boards in the United States alone, and thousands more abroad. Their ubiquity is no coincidence: federal law requires that nearly all research on people be vetted by a review board before it begins.\textsuperscript{17} Traditionally, IRBs have been housed within these institutions (hence the name *institutional* review board). Recently, though, private IRBs have cropped up, unattached to any “institution” per se. They are freestanding corporations that review studies for a fee. After all, to make an IRB you just need five experts, a record-keeping system, and the blessing of the federal Office for Human Research Protections, and this has left room for creative variation.

What we know about IRBs comes, primarily, from survey data and from firsthand accounts written by researchers whose proposals have undergone review.\textsuperscript{18} These sources have helped to create the general impression that
IRBs work slowly, demand study changes often, and are largely administrative.19 Fair enough.

In addition to being a troublesome part of researchers' daily grind, however, IRBs are also an example of a type of declarative body that fits into a wider system of governing with experts. Like other declarative bodies, IRBs have wide latitude in making decisions, so long as they make choices together. This social arrangement sets up a number of puzzles. For example, how do experts resolve disagreements, if each member has a claim to special knowledge? What sustains the impression that these people, together, are one uniquely empowered social actor? What, in sum, do knowledge experts take into account in their meetings behind closed doors?

I take up these questions in part 1 of this book, using IRBs as my example of a declarative body. Chapters 1, 2, and 3 are based on IRB meetings that I watched, audio-recorded, and analyzed at three sites for a stretch of time that ranged from several months (in the case of one medical board) to a full year (in the cases of two boards at different research-intensive state universities). I also interviewed the members of these boards and the chairs of different IRBs across the country, though I did not contact researchers or research participants, because of confidentiality concerns. (For more details, please see the appendix.) Appropriately enough, I had to get approval from IRBs at Princeton University and NIH for the research I did for this book. As I have come to know more about IRBs, they have become an avocation for me, as well.20

What I offer is a perspective from inside IRB meetings from the vantage point of a curious observer with no stake in the decision outcomes. What I learned was that the techniques IRB members used to reach decisions were strikingly similar at these different locations. To be clear, the IRBs I studied reached very different conclusions about similar studies. No surprise: they were working in different settings, were composed of quite different individuals, and made ample use of their discretionary prerogative.

But their methods for reaching decisions were patterned: board members tended to read researchers' application documents like tea leaves for signs of good character; to use warrants for expertise to justify their recommendations; to invoke previous decisions they had made as local precedents to guide future decisions; and, ingeniously, to use meeting minutes to manage relationships among board members and between board members and researchers under review.

Without planning or communicating, the various IRBs reached decisions using similar methods, and this, I argue, is a product of their common configuration. Starting in 1966, the U.S. surgeon general required all insti-
tutions that hosted research on people to get prior approval from a human-subjects review committee. This included universities, hospitals, and other organizations; and it covered both biomedical and social scientists. If the research was attached to public money, then this new policy was attached to the research. The model acquired teeth in 1974 when the Congress enacted regulation that required prior review (specifically, the National Research Act). The review model that was outlined in the 1966 policy and strengthened in the 1974 regulations came directly out of NIH.21

To understand how boards work today requires knowing how the research review model developed at NIH. How, for example, did expert deliberation come to be regarded as a sensible way to ensure upstanding research? Why did thousands of IRBs pop up at sites across the country, when the function could have been handled by a single federal IRB, as advocates urged, or by several regional boards, as in the UK?22

The story of how IRBs work is a story about their past, as well as their present. Typically, the origins of IRBs are explained through a series of scandals. The standard narrative often starts with the Nazi medical experiments during World War II. These atrocities prompted the 1947 Nuremberg Code, which set down on paper the ten moral imperatives that its American authors claimed all ethical researchers, like themselves, already knew. Twenty-five years later, the revelation of the long-running Tuskegee Syphilis Study on black men in rural Alabama triggered the National Research Act, which empowered the federal government to regulate research on people. The act also mandated a statement of principles on research ethics, which is known today as the Belmont Report. Casting further back, various accounts recall how doctors avoided misdeeds by observing the Hippocratic Oath; or explain how the 1930 vaccine tragedy in Lübeck, Germany, prompted research regulations even before the Nazis came to power; or recount how in 1966 Dr. Henry K. Beecher bravely exposed research abuses within his own profession.23 Starting in 2010, future histories will add the intentional-infection experiments on Guatemalans, who were given syphilis in the 1940s by American researchers.24

In the history of ethics, accounts of research scandals serve many purposes. They reveal the terms of political debate and the stakeholders relevant at a given time and place. Scandals serve as object lessons—shared memories with a moral, which are meant to teach people a common ethical sense in the present day. Careful histories of scandals also show how difficult it is to cast pure heroes and villains. Such accounts are important in that they can prompt political change and indicate the contours of a collective conscience.
One aim of this book, however, is to explain the content of political and intellectual changes. As a result, what I call critical-event narratives are less of a driving force in the chapters that follow than they are in other studies of research ethics. Instead, I explore how it came to be that groups of experts seemed well suited to make important choices about people’s rights. In chapters 4, 5, and 6, I explain how the moral authority to decide how to treat research participants was relocated from professions to the state and reinvested in procedures rather than ethics principles. I show how the practice of committee review within the NIH Clinical Center was created in the early 1950s to manage the unvarnished reality that NIH was hospitalizing healthy American civilians, in addition to sick patients, for medical research. The problems NIH leaders fretted over derived as much from a new kind of doctor, the “physician-researcher,” as from a new kind of patient, the “healthy patient.” In an effort to outflank federal lawyers and manage practical problems, researchers inside the Clinical Center developed a committee review system. The practice of expert review (or at least its rhetoric) was further entrenched in the late 1950s and early 1960s by researchers at the core of American biomedicine.

The model of group review was invented, justified, and expanded less by “outsiders” like bioethicists and activists than by the researchers themselves. The language of bioethics that has been read back into the history of IRBs belies their past as a technique for promoting research and preventing lawsuits. At NIH expert-review boards were crafted as an alternative to professional codes of ethics, which adhered to practitioners rather than to places of research. In contrast to the history often recounted in the bioethics literature, I give an on-the-ground story that shows how changes in the patronage of science affected research practices and moral sensibilities.

Because they bear the vestiges of this origin, IRBs today can enable surprising research practices. At the same time, they can restrict research in uneven ways. There is no dispute that the current research review system is flawed. On this everyone agrees: board members, administrators, and researchers. But the fact that IRBs provoke such heated debate is all the more reason to understand how these declarative bodies came into being and how they actually do their work. And so, on a dreary May afternoon, I stepped out of an elevator at Adams University Medical School, walked down a windowless corridor, and opened the conference room door where the IRB meeting was about to begin.
PART I

IRBs in Action

There are things IRB members are supposed to do: assess risks and safeguard participants' rights. Board members say that they do these things because they are moral imperatives and also because they are the law.

Then there are things IRB members do by virtue of the social arrangement created through these laws. It is hard for a group of people to assess the risks of research and safeguard the rights of participants while seated at a conference table, particularly when two crucial people are absent from the meeting rooms: namely, the researcher and the research participant. Researchers are absent from most IRB meetings by custom. Research participants are missing by definition: people cannot be recruited for research until after the IRB has approved recruiting them. Without the researcher and the subject, how do these decisions get made?

The chapters in part I take up this question and answer it in different but complementary ways. The aim of this introduction is to give a sense of what IRB meetings look like from the inside before showing how IRB members make decisions. My view is not the same one you will get from reading ethics training manuals. This is not to say that the IRB members at Adams, Greenly, and Sander State University were deviant or that their meetings went off script. The point, rather, is that IRB members have shared understandings about how to do their work, which they do not need to articulate. Their tacit understandings are in the background of the discussions that are on display in the subsequent chapters.

The Balancing Act

IRBs deliberate over a particular subset of studies during what is called full-board review. These were the types of reviews I observed in the meetings I
attended. Generally speaking, studies that are regarded as especially sensitive—potentially dangerous or possibly coercive ones, for example—are the studies that all the board members evaluate together, regardless of the research method. In addition to studies that receive full-board review, IRB administrators can place submissions in two other categories: “exempt” and “expedited.” The administrator or a few members can evaluate these studies independently.

According to federal regulation, the people who carry out full-board review have to fit a general mold. In terms of membership, IRBs must include at least five people. Some may have as many as twenty. The boards I observed averaged ten. The bulk of the members are supposed to represent “expertise” in the areas in which investigators propose to conduct their research, although no board member who is actually involved in the study under review may vote on it. There must be at least one board member who is not affiliated with the institution, and one member must have “nonscientific” concerns. Operationally, these requirements are often taken to mean that these members should not hold an advanced degree. In some cases, however, these members (sometimes referred to as “community members” or “community representatives”) do have formal research training, as was the case for doctors in private practice and theologians who served on the boards I observed. The National Bioethics Advisory Commission has recommended that one-quarter of IRB members should be community representatives and one-quarter should not be affiliated with the institution, but most IRBs fall short of this ideal. The federal government strongly urges that boards include at least one man and one woman, and it more gently encourages that members of racial minority groups be included on the boards, though the regulations do not, strictly speaking, set quotas for the race and gender composition of boards. As of 2002, one-quarter of IRBs had memberships that were exclusively white, and seven out of ten IRBs had male majorities. Within these flexible guidelines, local IRBs have the latitude to develop different standards and practices.

All members of the IRBs I observed had been appointed by a university administrator (e.g., the vice president for research); many saw themselves as fulfilling a service requirement; and a few had negotiated stipends or, for faculty members, course release. Most IRB members with whom I spoke reported that they served because they personally enjoyed it or because they wanted to serve as a “proresearch” presence on what is commonly considered a restrictive committee at universities. Perhaps institutions make the most of the resonance of “ethics work” with other kinds of activities that are thought to be altruistic but become morally suspect if money changes
hands: for example, donating blood, organs, or ova. By referring to board members' work as a gift—in their case, a gift of time—their choices can be made to seem more ethical and good. In any event, the board members whom I observed overwhelmingly described their group as very “compatible” and “collegial,” despite differences in training and personal background. This is no coincidence: members of declarative bodies tend to be selected not only for what they know and whom they represent, but also for a capacity that anthropologist Donald Brenneis calls “amiable mutual deference,” which smooths the deliberative process. The group members I observed worked to be accommodating of each other, in part because of this selection bias and also because board members get authority from federal regulations insofar as they act in unison as “the IRB.”

There are three moral principles—respect for persons, beneficence, and justice—that, in theory, guide IRB members’ interpretation of the nuts and bolts of regulations. When the Congress passed the National Research Act in 1974, it required that a national commission be created to review and ideally improve the laws for human-subjects protections that had just been enacted. That body, formally called the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, worked hard on many thorny issues (e.g., prison research) for many long years. One of their final acts, required by the 1974 law, was to articulate guiding principles for research on human subjects. In 1979 they published the Belmont Report (named for the conference center where the group met) to outline the overarching spirit in which the regulations should be interpreted. The commissioners decided that the three principles would come into play in three corollary practices: making sure that the people being studied were not chosen in discriminatory ways; ensuring that participants had adequate information when they agreed to be studied; and ensuring that the risks to participants (whether physical, social, or legal) were appropriate in light of the potential benefits of the study, either for the participants or for others. The shorthand for this final task, according to the Belmont Report, was to weigh risks and benefits. For IRB members, weighing risks and benefits of a study is a daunting task, in part because the commissioners themselves regarded it as an aspiration that could never fully be achieved.10

Why three principles, you might ask, and not four or four hundred? Sociologist John Evans has explained that this was a somewhat arbitrary choice but that it is a brand of arbitrariness that works well for modern liberal governments, in which the most seemingly impersonal decisions are taken to be the most legitimate.11 One way to make decisions seem impersonal is to use rational—that is to say, highly rule-bound—decision-making
techniques. Since the 1930s, rational decision making has taken the form of "balancing"—or cost-benefit analysis in one incarnation. It was not inevitable that cost-benefit analysis would become the main tool of rational regulatory decision making, but it has nonetheless become "the dominant logic of government." The aim is to encourage people acting on behalf of the government, whether they are rule experts or knowledge experts, to make decisions that either are based on numbers or seem to be.

As a result, the language of weighing risks against benefits is pervasive among IRB members, but board member rarely do—or even are able to—use quantitative balancing in any practical sense. In the 1970s, even the members of the National Commission recognized the "metaphorical character of these terms." Given that IRB members have (and use) a good deal of discretion when they evaluate researchers' studies, it may be reassuring to know that the commissioners themselves felt that "only on rare occasions" would "quantitative techniques be available for the scrutiny of research protocols." That said, the commissioners nonetheless felt that "the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible." The point of emulating a quantitative technique in what they acknowledged was an inherently qualitative assessment was to make the review "more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments." The commission's advice to IRB members—that they metaphorically weigh risks and benefits—may have had an effect precisely opposite to the one they intended.

The metaphor of weighing risks and benefits has come to serve many purposes in IRB meetings. At a Greenly IRB meeting, for example, the rhetoric of risk-benefit analysis oriented board members' thinking in the broadest sense and also added humor, irony, and reflexivity to reviews. In one case, a researcher recently hired by the university submitted a protocol for a study funded through the American Heart Association that involved enrolling older men at risk of a heart attack. Board members felt the researcher's protocol was too short ("a précis"), his information for participants too technical ("is it too much for a consent to be understandable?"), and his general demeanor "cavalier" ("He's from [another research university]. Maybe they're less demanding there."). More broadly, this lax kind of researcher was, in the board chair's estimation, an example of how the university was "getting new faculty, who are also very oriented to this type of protocol." One board member, Nathan, a reluctant bioethicist who preferred to avoid the tinge of righteousness by describing himself as just a member of the philosophy department, was concerned that these new researchers were not re-
strictive enough in their exclusion requirements for heart patients. A change to the research design would be entirely fair for board members to request, they decided, trying to shoehorn their good sense into the balancing metaphor. Here is an excerpt of the meeting that shows how IRB members use the rhetoric of weighing when deciding issues that do not register on scales. This excerpt also introduces some of the conventions that ethnographers use to designate in texts how people's conversations sound in real time. (For a list of transcription conventions and their meanings, please see the appendix.)

chair (University Research Administration): Nathan raises an interesting point because one of the things we are charged with doing is to determine whether the risk [is worth the—

edward (Faculty, Architecture): Risk is worth the benefit.

chair: Whether the uh =

Dr. Morris (Outside Physician): Benefit is worth the risk.

nathan (Faculty, Philosophy-Bioethics): Something like that.10

The language of weighing risks and benefits is more rhetorically useful, perhaps, than actual attempts to compare incommensurable things. Above all, it serves the purpose of demonstrating that a decision maker knows the rules of the game. Members of declarative bodies invoke regulatory language to show that they are aware of what they are doing, especially when they use their discretion to interpret the rules creatively.

Seeing Like a Subject

The people who do the day-to-day work of governing—who decide where to build a dam, a dump, or a sidewalk, for example—have a tendency, within some systems of government, to see only physical resources and the interests of power holders when they are preparing to make a decision. They tend not to see—not to imagine—the tangible consequences of their decisions for individual people on the ground who may be affected. Historian James Scott has called this phenomenon “seeing like a state.”17 Within the legal systems of modern liberal democracies, the people who do the day-to-day work of governing are encouraged also to “see like a subject.” In other words, rule experts and knowledge experts enact regulations that require them to imagine the perspectives of people whom the law is controlling or safeguarding. From the vantage point of a research institution, seeing like a subject is a way to reduce the chances that subjects will have reason to sue,
which they are empowered to do, based on laws such as human-subjects regulations.

One example of how regulations encourage IRB members to see like a subject is in locating the crucial threshold between studies that present "no more than minimal risk" to participants and more risky studies. The distinction hinges on whether the study presents greater social, legal, or physical risks than a participant would experience in her everyday life. The question for board members, then, is what the participant's everyday life is like, and whether the research involves experiences and procedures that are much different. If so, then the burden is on the researcher to show greater benefit.

What are the experiences of would-be research participants in their everyday lives, and how can you know? Previous studies on courts and on state administration would suggest that IRB members might think of research participants in the aggregate and of individual participants as microcosms of the broader population to which they belong. This was not the case among board members, though. To make decisions in IRB meetings, board members imagined the people who featured in their own lives as stand-ins for research participants. During an IRB meeting at Greenly, for example, an anthropologist on the board argued that children answering one researcher's proposed questionnaire would experience it as "invasive" because of the racial experiences of one of his own students. Earlier in the day, the student had told the anthropologist about how "when [the student] was two years old he was given a real hard time because he was sort of dark skinned but not quite clear. And he was being told, 'Are you black or white?' That is a good bit of concern. [Participants] should know that this is what kind of questions [they're] going to get." At another meeting, a sports coach on the board insisted that a researcher change the information that he was planning to give participants in a bone-density study. At issue was how best to express the risk of radiation exposure so that participants could consent with full information. That board member disliked the researcher's plan to express the radiation dosage relative to the amount from getting an X-ray: "When you say it's going to be / that it's the same as a normal X-ray—I mean, I can see my father going, 'How much radiation is that?" The people whom board members called to mind when they imagined a research subject—a relative or a student, for example—reinforced the race, class, and gender biases of the board membership. This often took place, paradoxically, during the review of studies that aimed to question conventional wisdom about health, social groups, and human experience.

Ambiguities over the boundaries of the groups that IRB members saw themselves as protecting and representing—that is, the slipperiness of terms
like community and population in IRB meetings—created situations in which all IRB members could usefully explain how their own life experiences might help the board more fully imagine the perspective of potential research subjects. At one meeting, for example, confusion over study recruitment snowballed because, a board member pointed out, it was unclear whether the phrase, “the control group will be recruited from the community” meant that the investigator would be “recruiting people here on the campus,” whether she would be “really looking at heart patients, the community of heart patients in this case,” or whether she would recruit from “the general community.” This same ambiguity over the meaning of community is inherent in the role of “community members” on the board. All IRB members could interject their opinions and warrants for their views through their claims to knowledge about participants by thinking of their friends, family members, students, neighbors, colleagues, and acquaintances. In this way, the membership of the IRB informs who is called to mind when board members imagine a research participant. (For more on the warrant of personal experience, see chapter 1.)

It is fair to say that neither researchers nor IRB members can know how each potential research participant will feel about the risks of a study or the adequacy of information about it. Given that people change their minds and often feel ambivalent, it is also fair to expect that participants’ own feelings about serving in a study will not be stable. As a result, the aim of human-subjects regulations (and in particular, the notion of informed consent) is to get potential research participants also to recognize themselves as “human subjects,” a legal category invented in the 1960s that now tends to be used to refer to anyone who participates in research. In sum, the review system aims to make sure that when researchers are studying people, each participant has come to see himself like a subject and that IRB members think of participants not in terms of populations, but as analogues of specific, tangible people whom they know in their daily lives.

**Housekeeping Work**

Quotidian as it is, research review often boils down to paperwork. To be sure, administrators do the thankless work of tracking and filing applications, forms, and e-mails between researchers and reviewers. But IRB members also deal with paperwork in a very different but nonetheless important way.

IRB members use the documents that researchers send to the board to judge the character of the researchers. For board members, the style and
tidiness of researchers' documents offer a snapshot of the person behind the application. Since researchers are invited to IRB meetings to talk about their studies at only 10 percent of American boards, the self-portrait that a researcher presents in her paperwork is often the only glimpse that board members get.

At Sander State, the board members liked to use the term *housekeeping* to refer to a particular kind of work they did during meetings—as in "There are a couple of housekeeping issues. The informed consent needs to identify this as a [Sander State University] study right up top" or (from a different member at the same meeting) "I have just a housekeeping issue here. The students are listed as co-investigators when actually they should be listed as key personnel." IRB members used the term *housekeeping* to refer to a type of paperwork that was a chore. No one relished making such changes, but they had to be made, like it or not: fixing typographical errors, correcting formatting glitches, and making other changes to produce clean documents.

When they did housekeeping work, however, board members and administrators were doing something essential to the review process. They were evaluating the researcher. It was through their reading and visual inspection of the documents, such as protocols, consent forms, and recruitment fliers, that board members developed their sense of whether they trusted the researcher. Since IRB members cannot oversee all studies as they are carried out, the group must be willing to trust that investigators are fastidious. When board members had reservations about a researcher, they gave the IRB a stronger presence in the research, for example by requiring that the researcher report to the board more frequently than is required by regulation or by selecting the study for an IRB audit.

Thus ink and paper served as character witnesses. At Greenly-IRB, for example, one board member, Dr. Morris, who was a head administrator at a local hospital, chided a researcher who misspelled "principal" in the subject heading of his protocol. In an interview after the meeting, I asked Dr. Morris to tell me how he goes about reviewing protocols when they come across his desk. Among other things, he volunteered that he looks for "misspellings" and other "editorial things" which "bother" him because such shortcomings demonstrate "a lack of attention to detail." Then he told me about the peanut butter phenomenon:

It's that old phrase, you never get a second chance to make a first impression. . . . I think that it colors the impression of the reviewer immediately. . . . One of my old professors, a long, long time ago, who was an internationally
known reviewer, called it the peanut butter phenomenon. He said that invariably when he got things to review, he would always find that somebody had spilled—this was twenty or thirty years ago—somebody had spilled some food on it and then left it. And he said, "This person has insulted me by not retyping the page even though they spilled their peanut butter and jelly sandwich." And so that was like an automatic "gone." You know, in the wastebasket. And I always remember him describing that, and I guess it's the extension of the peanut butter phenomenon. This is a person who's not careful enough to make sure that the word is spelled right.55

Why, specifically, is sloppiness relevant for research review? For Dr. Morris, "If [a researcher's] attention to detail is not sufficient to know that the major heading, the words aren't spelled right, I'm worried about [other things as well like], do I have to read this thing carefully enough to make sure that all the doses, for example, are correct, that they've written the protocol correctly. I wonder] where else is it sloppy? You know, four micrograms of nitroglycerin instead of point-four or four hundred micrograms of nitroglycerin. I mean, how careful do I have to be?"56 Similarly, a historian on the Sander State IRB described herself as "a stickler for detail" in protocol reviews. In addition to issues of confidentiality, she said, she was particularly attuned to "any inconsistency in the protocols, any of the specifics." She explained: "If it is an excessively sloppy proposal, I'm going to be more questioning about it. Even if the researcher thinks [the study] is potentially valuable, I do think they should be made to take care, take the time, get it right. . . . I would be prejudiced against it if it is full of typos, inconsistencies, factual errors that would make me doubt. I'd be questioning about the ability of the researcher."57 Board members parlayed the researcher's apparent attention to detail in documents into judgments of professional competence.

This was also apparent in meetings of the Adams Medical IRB. The university was in the process of replacing its old paper-based submission system with a new computerized system that allowed investigators to submit their IRB documents online. When errors appeared in investigators' documents—a recurring topic of conversation at the meetings—the board members did not simply note that the investigator needed to resubmit the materials. Instead, they tried to figure out who or what was to blame for the error: the investigator or the software. For example, after an IRB member, Dr. G., presented to the board what she regarded as a generally "weak" proposal, her comments begged the question of responsibility:
DR. G: [Overall, the proposal] needs to be much more clearly stated.
DR. K: Is this just a [software] error where they—
DR. C: I don’t know. Don’t know. It’s a very, very brief protocol, so—I know [the investigator] quite well. She was on call on this Saturday, and I was hoping /
DR. C: It’s a submission thing.
IRB CHAIR: Yeah.29

Board members were interested to know whether the software was causing problems so that the flaws in the system could be repaired (although there was a full-time staff member at the university whose job was to do just this). But determining responsibility for administrative errors also suggested to members of the Adams Medical IRB whether the researcher was properly supervising a study—giving subordinates too much responsibility or being careless when signing off on documents written in his name. Seemingly mundane aspects of the IRB review process are unusually important precisely because board members consider them appropriate grounds for judging the quality and integrity of investigators, whereas ascribed characteristics like race and gender cannot be used to judge researchers (though these factors are taken into account in selecting members of the IRB).29

Housekeeping work also helps to explain a curious feature of IRB meetings: when a researcher whose study is under review is also sitting at the table (or is on the other end of a conference call), then the review process is faster, not slower. Studies have found that the number of days between submitting a protocol and getting final approval is shorter when the investigator is present—even if the meetings themselves are not shorter by the standards of a stopwatch. In addition, when researchers attend meetings, there are fewer documents exchanged between researchers and board members: fewer letters, e-mails, and drafts of forms and protocols.30 When researchers are not present, IRB members not only invest more time in housekeeping work (and, ironically, demand more documents); they also use researchers’ paper trails to predict whether the researchers will follow the protocol laid out and actually prevent risks, protect rights, and deflect lawsuits.

Conclusion

IRB members were very good with worst-case scenarios. Supposedly, Americans have an easier time imagining good outcomes than bad ones, down to the finest detail. Ideal scenarios are somehow reinvented in the mind’s eye
as the most plausible outcomes. But this tends not to be the case for IRB members.31

The difference may rest with the fact that board members were not thinking about their personal futures during meetings. They were not discussing eventualities that were mostly within their control. Rather, board members were handed specific details about a future scenario that a researcher would be guiding and that would affect yet-unknown research participants. Strictly speaking, the task of IRB members during full-board review is to evaluate two things: whether researchers plan to observe participants’ rights (typically through “informed consent”) and whether researchers plan to keep any risks to participants in proportion to the expected benefits of the study. And yet board members have to be inventive in making decisions about people who are not present: researchers and participants. As a result, they made decisions through metaphorical “balancing,” by seeing like a subject, and through housekeeping work—practices that reinforced both the finest traits and the most unsavory biases of each board’s membership.
Local Precedents

Dissonant Decisions

Men who have been arrested and incarcerated have a significantly harder time getting a job than men with no criminal record. But the situation is especially difficult for black men. If a black man has been in prison, he is less than half as likely to be considered for a job than an ex-offender whose skin color happens to be white.¹

This is an important research finding. It is also a good example of how our notions of justice and our perceptions of public policies often change as researchers in medicine and the social sciences learn new things about individuals and social groups. Yet despite potential positive outcomes of this research, one could argue that the research methods were deceptive and unfair to the people being studied. The research involved sending fake job candidates—one white man and one black man—to apply in person for jobs advertised in a local newspaper. The men filled out the applications in identical ways. On some applications they said they had been convicted of a crime; on other applications they said they had a clean record. They made sure each employer got a good look at them. Then they waited for a phone call. The employers were under study, but they had never agreed to be the focus of the researcher’s gaze, and they wasted time and money screening bogus applicants.

Was it worth it? I would say yes, but others would disagree. Could it have been made a bit more fair to employers, who, after all, were not multibillion-dollar corporations but businesses trying to make ends meet in Milwaukee? When I asked this question to IRB chairs from large universities across the United States, almost all thought their board would have required changes to the study, if they had let it go ahead at all. I then asked, "How would the
researcher need to change the study?" Each answer to this question was as distinctive as the place where the board was located.

It is a puzzle—and a persistent problem for investigators—that different IRBs never seem to agree on how research should be conducted. It is a consequence of the unintuitive design of our current decentralized review system, in which there are as many IRBs as there are sites hosting research. This causes a serious practical problem for many researchers who face competing and sometimes contradictory judgments from several boards about how a single study needs to be modified before it can be approved. In recent years, the number of multisite studies that draw human subjects from several locations has been on the rise, and each institution has its own IRB that must approve the research. Imagine a clinical trial that recruits patients through hospitals across the United States because the disease under study is rare or because the trial requires thousands of volunteers. In these instances, several IRBs have jurisdiction over how the study is carried out. But regardless of location, all board members are following the same set of regulations. Then why do boards come up with different answers?

**What Would You Do?**

I asked the chairs of IRBs from eighteen major research universities from across the country how their boards would handle a study like the one on race-based hiring discrimination against ex-offenders. The IRB chairs gave very different answers, but they also gave hints as to why IRBs apply the same set of regulations to the same proposals in different ways. Their responses suggest a way to rethink how expert bodies evaluate research and help to explain why IRBs, in particular, arrive at different decisions about the same study.

As the board chairs thought through and talked about the protocol, they did one of two things. Some chairs tried to apply the general human-subjects regulations to this specific case, remarking, for example, that they would "go to the guide book, and look and see what it says about that." One chair stated that she would consult the regulations and "follow the guidelines for research that governs deception." These board members were looking at the proposal with fresh eyes and were inclined to translate general rules so that they could be applied to this specific case, as if for the first time.

Other board chairs saw problems and proposed modifications to the protocol because they recognized it as similar to a memorable study or problem that they had already seen, debated, and resolved. That is to say, they tried to work from an exemplary case to this specific case. Among dif-
ferent communities of researchers, IRBs naturally end up reviewing different protocols, and so each board has its own set of exemplary cases that guide their evaluations of subsequent studies. For the board chairs whom I interviewed, this meant that the standard protocol that I gave them represented widely divergent concerns, based on the particular set of protocols they had reviewed and decisions they had made in the past.

Here was the question: What would your IRB do in this situation?

Your committee receives a proposal that requests approval for a field experiment. The researcher wants to learn whether employers discriminate against job candidates who are black in comparison to job candidates who are white. The experiment involves black men and white men who are confederates of the researcher and who fill out job applications, preferably in front of the employer, at places where blue-collar jobs have been advertised. The researcher’s confederates are trained in advance to behave as similarly as possible. They leave a phone number on the job application. The researcher’s dependent variable is whether the confederate gets a call about the job from the potential employer.6

It is not apparent from this vignette when or how the researcher might ask employers’ consent to include them in the study. Today, informed consent is widely considered to be the foundation of human-subjects protections (though this seemingly intuitive marker of good ethics took on its current shape very recently; see chapter 5). That said, federal regulations do allow IRBs to waive consent for an investigator doing some types of research if the study cannot be carried out in any other way and if the study poses risks that are no greater than what the research subject would experience in his everyday life.7

IRB chairs’ responses to this protocol ranged widely. “Would we approve it? Yes,” one chair replied decisively. “I think this is a pretty cut and dried scenario to tell you the truth.”8 Others were much more ambivalent. “I suspect that this is not something that would go through,” another concluded, “This would be extremely problematic.”9

Although the IRB chairs gave different answers to the question of how the protocol should be handled, they gave compelling justifications for why their board would make a given decision. They did this by recognizing the protocol as an example of a type of research that their board systematically managed in a certain way, as one chair indicated when she immediately spoke of the study in the plural. She remarked, “We are very sympathetic to these,” by which she meant studies like an analysis of school quality that
her board had approved because it was of "social value" even through it
involved deception. "Basically, we're inclined to approve them."

The studies that boards had reviewed in the past not only shaped reme-
dies to ethical concerns but also guided the problems that board chairs read
into the protocol in the first place. The chair who had described this study
as "extremely problematic," for example, identified risks in the protocol
beyond those recognized by most chairs. Like others, she argued that there
were serious legal risks to the employers being studied if the investigator
breached confidentiality and it became known publicly that certain employ-
ers were discriminating against job candidates. From her perspective, how-
ever, there were additional risks. She identified the protocol as analogous
to research that her committee had previously considered that put at risk
not only subjects, but investigators and the university as well. "I can imagi-
ne if you're someone accused of discrimination, you're going to pursue
this and [possibly even] sue the researcher. So one thing that we're careful
about—We have people who are doing research studies on sex workers, say,
or transgender people, who are often in high-risk areas and environments
carrying out their research. And we're as concerned about the safety of the
researchers as the subjects in this case." Thus she felt that her board would
see the proposed study as posing risks to the researcher as well as to the
subjects, even if those risks were legal rather than physical. She continued,
"We'd want to make sure that the person doing this research was protected
as well." The added protection that her board would require before ap-
proving the protocol might include a federal certificate of confidentiality for
the study, which only one other IRB chair proposed.

The primary concern for a different IRB chair was the validity of the
research. "We had a study where they were basically doing something very
similar to this except they were going to have policemen come by to see if
they actually stopped to talk to people or not, depending on whether they
were African American or not." His board felt that the study, as originally
proposed, was not well designed. "The problem is," he explained, "you
might find out about that one [policeman], but if you want to generalize
from this whole study that you're doing [to say] that the police department
is this way, the problem is that you didn't actually have all possible police-
men actually do this." This experience with problems of study design in
field research had implications for the standard protocol I gave him: "In this
particular case, you're really only studying a small number of people. . . .
There are a lot of study protocol things that would have to be there for this
to be considered a valid piece of research."
Most board chairs identified informed consent as a concern, but they diverged dramatically on what modifications they would require. One IRB chair saw prior consent as not only possible, but valuable in this protocol because it would both protect the subjects and serve as the ethical linchpin that would allow the research to meet federal regulations without compromising the study design. This was possible in his view because his board had developed an almost formulaic way in which it required investigators to get subjects’ consent in deception studies. “We’ll say you can describe things in a general way and not be specific, like ‘We have a study of attitudes.’ And you make them think it’s about the passage they’re reading but it’s actually the pictures that accompany the passage and so on. We’d have real problems with your walking in on somebody and not even making them a willing subject of research.” This meant that his board would not approve the study “as it stands” because the employers would not know they are being researched, but if the research got “some kind of prior consent by the party,” then his board would likely approve it. He knew from experience that this was entirely possible.

An anthropologist serving as her IRB’s chair saw the lack of informed consent as a problem for the study, and yet, try as she might, she could not call to mind a similar study to guide her. Her response is revealing: “Here’s some really important research, but my god, there’s no consent here. And if there were consent, it wouldn’t be worth anything.” She concluded, “I just don’t see how we could approve that,” and then, turning the question to me, asked, “Do you?”

She was one of several board chairs who asked me not what the “right” answer was to the standard protocol, but, in the words of another chair, “How have other people been responding?” When the protocol did not conjure up an exemplary study or problem that the board had previously settled, chairs at times turned to the regulations for guidance, but they also tried to learn about other boards’ decisions for a precedent they might adopt. (Tellingly, members of the boards that I observed also asked me how the other boards that I studied handled a problem that they were facing for the first time.) I described to the anthropologist the response of an IRB chair on the East Coast who had proposed that deception “is not necessary in this case.” She had recommended telling subjects during the recruitment and consent that sometime in the next year, an imposter job seeker would fill out an employment application. She had found that this strategy had worked well in her own research on discrimination in health care because “[if] you let enough time lapse … [subjects] return to their normal behavior.”
Hearing this solution, the anthropologist changed her answer, agreeing with delight, “I think that’s reasonable.”

In the end, all but one chair reported that they could envision a scenario in which the board would allow an investigator to conduct this study if he made certain changes and concessions. However, the chairs diverged on whether they turned to the “rule book” or drew on a resonant past experience. They also diverged in their interpretations of the problems with the study and the modifications that they requested. Because of their unique caseloads prior to my interview, IRB chairs had different views about what risks the standard protocol entailed, who would be at risk, and what the severity of the risk would be. This previous experience guided them toward distinctive decisions about whether consent could be waived, whether investigators could get consent without invalidating their data, and whether debriefing should be mandatory or prohibited as a source of harm in its own right.

Explaining Dissonance

Surveys agree: when different boards are presented with the same standard protocol to review, the boards will unfailingly arrive at different judgments about how the protocol needs to be changed before they will approve it. Survey results, however, have fallen short in explaining why this happens. Authors of these studies tend to view variable decisions as the product of uneven resources across boards. They suggest that with larger staffs, more time, and better training, all boards would arrive at the “correct” decision about a protocol. Locating the source of uneven decisions in uneven material resources does have some merit, and it is certainly a compelling explanation when looking at the externally measurable features of IRBs, such as budgets and decision outcomes. These are only partial explanations, though. Even if IRBs had comparable amounts of funding and staff time at their disposal, they still would not produce wholly consistent decisions.

This is because the differences between IRBs rest not only with their material resources, but with their conceptual resources. The application of general rules to specific cases is always an act of interpretation, since concepts like risk are not inherently meaningful. Recall that to establish working definitions of abstract regulatory terms, IRB members warranted their views about the right course of action when a proposed study presented them with a new puzzle (chapter 1). Another tool IRBs used to reach decisions, the current chapter shows, is to invent the perception of familiar cases. Expert bodies can ease the burden of review by dealing with their workload in
a routine way: speedily, consistently, flatly. Routines have to be established, however. They emerge through practice over the course of time.

Each board imprints the studies they review with their common knowledge and experiences as a group. Boards treat many reviews as routine encounters with familiar cases that they know how to handle. This sense of recognition of new studies that, strictly speaking, board members have never seen before marks the importance of board members’ shared experiences that serve as the group’s common ground. In these circumstances, boards are not working from general rules to specific cases, but from exemplary case to specific case.

I call these exemplary cases local precedents. I use this term to describe the past decisions that guide board members’ evaluations of subsequent research. By drawing on local precedents, board members can read new protocols as permutations of studies that they have previously debated and settled based on members’ warrants. The result is that IRBs tend to make decisions that are locally consistent over time. Whereas board members used individual-level warrants to justify their views to each other, local precedents can be thought of as shared warrants that compel the board as a whole. The important feature of IRBs’ local precedents is that they tend to be idiosyncratic to each board but reasonably stable within them, which explains how two well-supported, fully functioning IRBs can arrive at different decisions about the same protocol.

Local precedents can be observed only if IRBs are seen as groups developing over time. This feature of IRBs brings together two insights: first, that small groups develop distinct ways of understanding and acting in the world, and, second, that the timing and order of events structures the paths that people choose to take in the future, a sort of rambling path-dependency.19 Tying these two threads together, expert bodies have their own histories that shape their distinctive ways of understanding the empirical world.

**Local Precedents**

After the Sander State IRB discussed an adverse event in a study that they had previously approved, a psychologist on the board, Ken, pithily reflected on the board’s new position toward subject recruitment: “Sometimes things have to happen before you know what to do in the future.”20 Ken’s observation flags the process in which board members used one evaluation as a stock decision to judge new protocols. Far from applying federal regulations afresh to each new study, they instead identified most new studies as
examples of problems they had previously solved. IRB members develop and use local precedents to smooth or speed their future decisions, allowing local boards to make more efficient and internally consistent decisions over time. By the same token, this process is responsible for the variability and inefficiency across IRBs that many critics lament.

In the IRB meeting at Sander State that Ken was reflecting on, board members had been considering investigators’ use of what are called opt-out forms in recruiting participants. Investigators can give opt-out forms along with regular consent forms to people invited to participate in a study. If a person does not want to participate, she can send the opt-out form back to the investigator rather than not return the regular consent form. Opt-out forms are generally considered an advance in human-subjects protections because they give people more agency, but many board members have reservations about them because they also force people to respond to a study (if they don’t send back a form, either the consent form or the opt-out form, they receive a follow-up call). Views of how investigators should use opt-out forms in their recruitment of research participants varied across the IRBs that I observed.

At Sander, IRB members had always allowed investigators to carry out what seemed to be a common practice: to call potential research subjects on the phone if they did not return a consent form that the investigator had mailed to them. That said, the practice had not passed without remark among board members; they periodically raised questions about whether this aggressive recruitment strategy compromised people’s privacy for the sake of higher research enrollment. In their December meeting, for example, the Sander IRB reviewed a study in which the investigator proposed to examine the effectiveness of a behavior-management course for children who showed signs of developing an attention deficit disorder. The investigator planned to have school children carry letters home to their parents introducing the study and asking the parents to return the consent form if they wanted to have their children screened for the disorder and possibly enrolled in the course. If parents did not want to have their children involved in the study, they were instructed not to return the form. However, Nigel, a humanities professor on the board, observed that everyone who did not want to participate in the study would also get a phone call asking whether she had received the information and, again, whether she and her child would like to participate. Nigel pointed out, “It says not to return the form if you’re not interested in participating.” The investigator assured the board that the research team planned to call just “to make sure” that the person had clearly decided not to participate, but Nigel wondered, “Is this an
invasion of privacy?" The investigator suggested that an unreturned consent form might indicate simply that a parent had misplaced the document, not that she was uninterested in the study. With this explanation, the IRB chair moved the discussion onward.21

Two months later, at its February meeting, the board was due to renew its approval of a study examining how people with depression managed their condition. The investigators in this study screened tens of thousands of people to find potential volunteers, some of whom were contacted using the records kept on people who had been prescribed antidepressants. A small number of these people complained about the phone call that they received asking whether they wanted to participate in the study. None of the people who complained had received the letter sent to them in advance, introducing the study, along with an opt-out form. The phone call was the next step in the investigators' protocol to pursue potential subjects who had failed to reply either that they were interested or that they were uninterested in participating.

Preempting any IRB decision about whether or how to proceed with the research, the investigators in this study abandoned their strategy of using opt-out forms altogether. They enrolled only people who actively returned consent forms and did not call people who had not sent back their forms. They made this change because the nonconsenting people either would have opted out or they would have been subject to what was now being framed as an invasion of privacy if the investigators called to follow up. The investigators knew that this would reduce the number of subjects they would enroll. They hoped that they would still get enough subjects to run their statistical analyses, perhaps believing that their own conservative solution to the adverse events would be better than remedies that the IRB could require. Assessing the problem and the investigators' response, the IRB agreed that the new plan was the right solution. Furthermore, board members decided, in the words of one member, "We now have a new methodology . . . for similar situations."22

It is worth noting that the IRB's "new methodology" emerged to address a practice that they had seen in the past but had never fully considered a problem. This case suggests that complaints from potential recruits and active participants, as well as proposed solutions from investigators, can prompt IRBs to identify and then settle problems that serve as exemplars going forward. The role of investigators in shaping local precedents—which are the solutions that subsequently guide decisions on similar problems—is striking in comparison to investigators' loss of influence over decisions after precedents are set. Investigators can guide IRB decisions, then, but most
effectively during the critical moments when IRBs are settling newly problematized human-subjects concerns.

Once a local precedent started to crystallize—which was only apparent when board members applied a one-time decision for the second time to a new case—board members tended to read subsequent protocols in light of the past decision. The Greenly IRB, for example, pieced together a local policy for how investigators can “re-contact” former subjects without their consent. The philosopher on the board, Nathan, had gently raised this issue in the past, suggesting to an investigator during the board’s April meeting, “Looking ahead, you might want to do a follow-up study, so you might want something in the consent to allow you to re-contact them.” The conversation started and ended there.

The next month, however, the board was faced with an urgent recontacting issue that proved difficult for them to resolve. An investigator in child development had planned a new study around the assumption that she would be allowed to call her former subjects to recruit volunteers. This would give her a rich data set, because she could merge the new data with participants’ responses from her previous study. Technically, Nathan argued, this was a breach of an implicit contract with the participants, who had previously consented to have their contact information used for one study and had not formally agreed to be identified and sought out again. He asked the investigator, “How much of a pain would it be to change your recruitment given that you haven’t had permission to re-contact?” Recruiting a new set of subjects, though possible, would severely limit the usefulness of her proposed study, the investigator replied.

Board members weighed different options. One possibility was to have the investigator send her former subjects a letter introducing the new study, before calling them to ask whether they would participate. Another possibility that a board member came up with in his effort to “think creatively” was to send a letter introducing the study and an opt-out postcard that people could send back if they did not want to get a recruitment phone call. While board members felt bad that either of these recontacting strategies would reduce the investigator’s enrollment, many also felt that these solutions were less intrusive than unannounced recruiting phone calls. Other members rolled their eyes at these suggestions.

“I think we’re making this a bigger thing than we need to,” Edward said. Donna, from the Sociology Department, agreed: “I don’t think that it’s the board’s responsibility to protect people from any minor annoyance. I think that we (should) balance risk against (benefit), and I think that the risk is so minute in this instance that I would say (you should just contact people).
For the future, perhaps, (include language asking whether you can) contact
them in the future." Nathan agreed that the annoyance of being recontacted
would be "trivial" and that his colleagues had suggested sensible alternatives.
Nonetheless, Nathan said, the problem remained that the IRB was
condoning the investigator's breach of contract, and he reminded board
members, "We haven't answered the first question, which is whether we're
okay with breaching these obligations in the first place, or whether there's
any way of making this not a breach of those obligations." Adding to the
group's ambivalence, the board chair informed other members that allowing
this to proceed could cause trouble in the research office, reporting, "We
do get phone calls from people who do not want to be called again. I can
guarantee you, we get those... They're very real."

In the end, board members agreed that the investigator would be al-
lowed to break the letter of the law. In the words of the IRB chair, "If there
is a problem, this is where we'd have to say to the government, 'Sorry, we've
done something incorrectly,' and get our hand slapped." At the same time,
board members recognized that by thinking of this as an exception, they
had created a new rule. "We learn from the past, but we can't change the
past," a physical therapist on the board summarized, "We can say okay this
time, but from now on we're going to do this."

The IRB's struggle over this individual protocol had broader implica-
tions, in the minds of board members. "I'm surprised how long the con-
versation has lasted," a psychologist reflected, prompting weary chuckles
from his colleagues. "But I think it was a good (conversation) because what
comes of it is, I think, is a new policy. It's not going to apply just to [the in-
vestigator's] research, but to anybody else who does this kind of stuff, who
wants to go back to participants. So I think it's really cool."

The June meeting of Greenly State showed how this "new policy" entered
board members' repertoire as an exemplary decision that could guide future
studies. A new investigator in physical therapy planned to keep enrollment
information on his subjects, and to Nathan this looked distressingly famil-
 iar. Nathan wondered whether the investigator kept the information be-
cause he intended to recontact these subjects, but the investigator assured
the board that this information would be used solely to help compare data
from other subjects to the data he hoped to collect in his proposed study.
"That's fine," Nathan concluded. "I got a bit scared the last time we had a
meeting about the other uses of information you keep during the course of
a study," he explained. If the investigator wanted to contact participants in
the future, he would have to tell them now.

Creating local precedents was time-consuming for board members, and
they often pursued issues for unpredictable reasons, such as a board member’s personal conviction or a research subject’s complaint. Once settled, however, IRB members used these decisions in a systematic way to guide future decisions. In this way, the boards that I observed standardized the types of problems they identified and the changes that they required to protocols, such as the units in which radiation levels should be expressed, how psychological inventories should be described to subjects, and the number of years for which a study’s approval could be renewed, to name a few. The effects of these local precedents were twofold: first, established precedents allowed board members to make subsequent decisions more quickly without rehearsing settled debates, and, second, the precedents allowed members to defend their decisions on the grounds that they were imposing a consistent local policy.

Conclusion: Decision by Analogy

IRB members identify new problems somewhat idiosyncratically. For these problems, board members develop remedies to fit the particular instance and draw on the warrants of experts who happen to be at the table. But IRB members also use these decisions as prototypes that they apply to subsequent protocols, creating local precedents. When board members identify a problem in a new study proposal (or an element of it, such as the consent language or the research design), they do not try to apply general rules afresh to the specific case; rather, they apply the solution they came up with for a previous study to the new case at hand. Thus, local precedents are stock decisions, which board members use to manage subsequent protocols and speed future reviews. The decisions that establish local precedents are idiosyncratic, but once made, an IRB’s decisions are quite stable and predictable over time.

This description of how IRBs make some decisions contrasts with the assumption that expert bodies deliberate within the framework of what has been called legal positivism. In this view board members are thought to apply fixed regulations to specific protocols with more or less accuracy, resulting in objectively right and wrong decisions. It is worth noting that many such analyses of IRBs are written by medical and health researchers, who in their main areas of research tend to aspire to the positivist ideals of experimental methods. However, their experimental style of reasoning, to use Ian Hacking’s phrase, does not characterize how IRBs reach decisions.29 The way IRBs work, as I have described them, resonates more closely with what historian John Forrester, in his extension of Hacking, has called
analogue reasoning. Forrester argues that "thinking in cases" stems from
a pragmatic, not an experimental, tradition that was developed in Anglo-
American law and medicine during the late nineteenth century. "If you
think that invoking principles will avoid this method of reasoning," For-
rester writes with particular reference to case-based decision making in
modern medical ethics, "a skeptic of the relevance of your principles will
soon require you to make explicit the exemplar, the prototype, the analogue
onto which the invocation of your principles is grafted."30

Overturning the received wisdom about how IRBs make decisions helps
explain several puzzles about these expert bodies, such as the way board
members described their colleagues to me. IRB members valued experi-
enced colleagues for providing the board's institutional memory, and they
reported that new members (and they themselves) had to serve on the board
for roughly a year before they were competent reviewers. I take these to
be descriptions of how IRBs maintain continuity over time through case-
based learning. As historian Thomas Kuhn has argued, people learn how
to recognize and solve problems in a new field of study not by memorizing
abstract rules. Instead, they are taught how to solve model problems—what
he called exemplars—which allows them eventually to internalize the tacit
knowledge and the thinking skills common among members of the field.31
Through these model problems, students learn to distill an essential point
from a mass of irrelevant details and figure out what constituted an appro-
priate question in the first place. Similarly, IRB members use exemplar
protocols and problems as sources of model decisions that allow them to
"do ethics"—to identify a subsequent protocol's essential problem amid all
of its particulars, to recognize its similarity to a prior case, and to make a
consistent decision. If IRB members were always applying general rules to
particular cases, as some critics assume, rather than working from case to
case, it is not clear what would be worth remembering or learning over time.
Certainly, members pass on and become fluent with norms of group par-
ticipation.32 However, it seems that experienced board members also pass
on the substance of prior decisions to new members, who have to learn at
least some of the group's local precedents before they feel competent as
reviewers.

Understanding group decision making in terms of case-based reasoning
also helps explain why some IRBs belabor decisions that other boards make
more quickly. Critics and regulators often attribute this variation in effi-
ciency to an uneven distribution of material resources. I do not dispute that
if a board has more full-time staff and funding, it will make speedier deci-
sions. I want to add, however, that differences in boards' turnaround times
are in part due to differences in their conceptual resources. As I have shown in the previous sections, settling contentious questions is time-consuming for IRBs: members distill a distinctive case to what they see as its central problem, then debate the proper decisions according to their individual sensibilities. It seems likely that differences in boards’ decision-making efficiency with a given protocol depend on whether members have already established precedents to manage the concerns at hand. For example, the drawn-out deliberations of an IRB made up of medical researchers when faced with a qualitative study may not reflect hostility toward qualitative methods. Rather, it may point to a conceptual gap in the precedents readily available in board members’ imaginations to deal with the type of concerns that they feel the study raises. Indeed, sociologist Carol Heimer links the speed of case-based decisions to the existence of precedents. She argues that thinking in cases requires a regular flow of instances that can be seen as examples of a prior case and that inefficiencies crop up in situations when “case streams do not exist . . . [such as] when something is being encountered for the first time.”

On a practical level, understanding how case-based reasoning affects IRB deliberations points to ways in which local boards might eventually coordinate their decisions across different institutions. A simple infusion of staff members and funding will not erase the variation across IRBs that trouble many investigators, especially those conducting multisite studies. Investing more time and money in human-subjects review will, rather, improve the speed with which IRBs continue to arrive at dissonant decisions. Consolidating boards will serve to decrease the number of idiosyncratic IRB decisions investigators have to manage but will not eliminate these particularities altogether. IRBs would make more similar judgments if local boards shared decision-making precedents at a national level. Given that IRBs make decisions based on cases, the challenge for a coordinated review system is not to craft more detailed federal regulations, but to train IRB members with a common set of real cases on which boards can base their decisions, as an alternative to local precedents.

It was a fortunate decision, but by no means a foregone conclusion, that the IRB at the University of Wisconsin, Madison, approved Devah Pager’s protocol when it came to the board in 2001. Pager was the researcher behind the employment and incarceration study in Milwaukee described at the beginning of this chapter. She had heard from other researchers that the Brandeis University IRB categorically refused to approve this kind of study design. It was felicitous that the University of Wisconsin IRB had no local precedent of its own, and so its members assessed the study with fresh eyes,
which turned out to be sympathetic. They did require one change, though. Pager had planned to debrief employers after the study, in keeping with a more conservative reading of the regulations. The board members asked her not to debrief her research subjects. There was little risk of harm to participants, they reasoned. And if employers never knew they were in the study, then they would never be able to sue.