

Righting Research Wrongs: An Empirical Study of How U.S. Institutions Resolve Grievances Involving Human Subjects

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ABSTRACT

Tens of millions of people enroll in research studies in the United States every year, making research a multi-billion-dollar industry in the U.S. alone. Research carries risks: although many harms are inevitable, some also arise from errors or mistreatment by researchers, and the history of research ethics is in many ways a history of scandal. Despite regulatory efforts to remedy these abuses, injured subjects nonetheless have little recourse to U.S. courts. In the absence of tort remedies for research-related injuries, the only venue for resolving such disputes is through alternative dispute resolution (ADR) — or more commonly, *internal* dispute resolution (IDR) through a process offered by the research institution. The federal regulations on human subjects are silent on resolving subject grievances, and to date, little is known about how institutions handle these disputes. This Article is the first empirical study of how U.S. universities and hospitals resolve subjects' claims of physical injury, dignitary harm, non-compensation, deviations from research protocols, and maltreatment by research staff. I have conducted in-depth interviews with personnel from 30 hospitals and universities to understand how institutions respond to grievances involving research subjects. These interviews reveal highly flexible dispute resolution processes managed by institutional review boards (IRBs), the institutional authorities mandated by federal law to protect human subjects. Although many interviewees spoke intuitively of procedural justice—including elements such as voice, neutrality, and courtesy—these interviews also indicated problems with neutrality, expertise, representation of participants, one-sided appeals, and access to the dispute resolution process itself. This Article takes a close look at current practices, and then suggests strategies for improvement, addressing both the federal regulations and options for institution-led reforms.

I. INTRODUCTION

Research is an enormous enterprise; more than 19 million individuals participate in research studies per year,¹ and the annual costs of research in the U.S. include an estimated \$32 billion in NIH funds² and over \$50 billion in pharmaceutical funding alone.³ Although federal regulations, state laws, and professional organizations apply countless mandates to institutions that conduct human subjects research, the processes for resolving research participants' concerns are a curiously unregulated space. Where grievances arise, U.S. courts have recognized claims relating to physical injuries, negligent study design and oversight, and insufficiency of informed consent.⁴ But courts cannot and do not respond to most research-related injuries. Litigation is procedurally unavailable for large classes of research participants, such as international subjects or subjects in intramural federal projects.⁵ Moreover, many research-related disputes are not amenable to courtroom remedies. Recent work suggests that there is a high frequency of non-justiciable complaints in healthcare settings,⁶ and a few such concerns in research may include study staff rudeness, offensive recruitment efforts, or post-trial access to study drugs. Prior findings suggest widespread confusion among subjects about study protocols,⁷ and this confusion may engender other subject complaints. Where litigation is not feasible, or where complaints are not cognizable in courts, institutions may seek to provide alternative fora for resolving research-related disputes. These ADR practices, however, have gone entirely unnoticed by scholarship.

Responsiveness to research subjects' injuries and complaints is a legal, ethical, and practical imperative for research institutions. At institutions that receive federal funds for research, federal regulations governing research with human subjects (the "Common Rule") delegate oversight over research protocols to institutional review boards (IRBs). IRBs are tasked with *a priori* review and approval of research protocols, after determining an appropriate balance of risks and benefits, equitable selection of subjects, and reviewing procedures for securing informed consent from participants or their legally authorized representatives.⁸ In approving and monitoring protocols, U.S. IRBs often take as their guiding principles those set forth in the Belmont Report, a 1979 set of guidelines issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Although the Common Rule does not specify the procedures that

¹ Adil E. Shamoo, *Adverse Events Reporting—The Tip of the Iceberg*, 8 ACCOUNTABILITY RES. 197 (2001)

² NIH, Budget, <https://www.nih.gov/about-nih/what-we-do/budget>

³ PhRMA, 2015 http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf

⁴ Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229 (2003)

⁵ Elizabeth R. Pike, *Recovering from Research: A No-Fault Proposal to Compensate Injured Research Participants*, 38 AM. J.L. & MED. 7 (2012);

⁶ Orna Rabinovich-Einy, *Deconstructing Dispute Classifications: Avoiding the Shadow of the Law in Dispute System Design in Healthcare*, 12 CARDOZO J. CONFLICT RESOL. 55 (2010)

⁷ James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review*, 292 JAMA 1593 (2004); Matthew E. Falagas et al., *Informed Consent: How Much and What Do Patients Understand?*, 198 AM. J. SURGERY 420 (2009); Adam Nishimura et al., *Improving Understanding in the Research Informed Consent Process: A Systematic Review of 54 Interventions Tested in Randomized Control Trials*, 14 BMC MED. ETHICS 28 (2013).

⁸ 45 C.F.R. § 46.111 (2017).

institutions must use when grievances arise during research, federal regulations do require that participants receive “an explanation of whom to contact . . . in the event of a research-related injury.”⁹ This implies that responding to such contacts is indeed a legal imperative for research institutions, and most institutions house that responsibility within the IRB.

As an ethical matter, the duty to respond to participants’ concerns over the course of research follows from the Belmont Report’s emphasis on respect for subjects’ autonomy, justice and the equitable selection of study subjects, and minimization of research burdens (beneficence and non-maleficence).¹⁰ Because unforeseen problems may arise during research studies, each of these ethical goals requires that when participants allege injuries or grievances, institutions responsible for conducting research must remain responsive to these ongoing problems. Several scholars have noted that “researcher ethnocentrism” can limit researchers’ ability to identify ethical problems in their own protocols, and researchers sitting on IRBs may be no different;¹¹ providing a feedback loop for subject complaints is an essential means of augmenting IRB review and oversight. As a practical matter, providing a forum for the resolution of research-related complaints may avert litigation, identify unforeseen problems in research protocols, promote stable relationships between research institutions and communities who may participate in research, and encourage participation among subjects who may be concerned about accountability in the event of injury.

Prior literature suggests that research institutions do, in fact, maintain internal processes for the resolution of research-related disputes, and IRBs provide these procedures as part of their research oversight role. But almost nothing is known to date about how these processes work. Scholarship on internal dispute resolution (IDR) systems—dispute resolution procedures maintained internally by corporations or other institutions—reflects concerns about procedural fairness. When one party to a dispute has structured the process by which that dispute is resolved, there are many opportunities to build institutional advantage into these procedures.¹² The need for procedural fairness is keen when parties waive claims and other venues, such as an agreement not to sue, or when other venues are unavailable from the outset (e.g., because litigation is unavailable, or because the complaint is not legally cognizable). IRBs themselves are in a curious role. They have a federal mandate to protect subject well-being, independent of the institution, and the institution may not authorize research that lacks IRB approval. IRBs do not do research themselves, and their practices and decisions are rarely the subject of subject complaints. They are thus infrequent “parties” to the disputes. But IRBs are nevertheless institutional bodies and composed largely of institutional employees and staff, and they are not blind to institutional liabilities. This Article will therefore consider IRB-managed processes as “internal” to the institution, despite IRBs’ independent grant of authority to approve and oversee human subjects research.

⁹ 45 C.F.R. § 46.116(a)(8) (2017); under the new rules in 2018, this will be 45 C.F.R. § 46.116(b)(7), but the language is unchanged.

¹⁰ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education & Welfare, *The Belmont Report* (1979).

¹¹ REBECCA DRESSER, *SILENT PARTNERS: HUMAN SUBJECTS AND RESEARCH ETHICS 2* (2017).

¹² Lauren B. Edelman, Christopher Uggen & Howard S. Erlanger, *The Endogeneity of Legal Regulation: Grievance Procedures as Rational Myth*, 105 AM. J. SOCIOLOGY 406 (1999); Mark Galanter, *Why the “Haves Come Out Ahead: Speculations on the Limits of Legal Change*, 9 L. & Soc’y Rev. 95 (1974).

This Article proceeds on the premise that providing *procedurally* just grievance procedures in human subjects research is an entailment of the ethical duty to provide resolution to research-related complaints and injuries. Importantly, IRBs enact and implement these systems amid long-standing power imbalances between researchers, research institutions, and participant communities. The history of research abuses worldwide is long, and biomedical research in the U.S. has provided some of the most acute examples of studies that violated subjects' rights, autonomy, dignity, and humanity.¹³ The current regulatory system is intended to curb these abuses, bolstered by ethical guidance such as the Belmont Report, the Declaration of Helsinki, and the Nuremberg Code. But despite these regulatory frameworks, power disparities between participants and research institutions persist. This is in part a result of epidemiology. The burden of ill health, and the risk of ill health, is unevenly distributed along lines of socioeconomic status, race, ethnicity, education, disability, and other axes of social marginalization.¹⁴ Research protocols for the study of disease prevention, etiology, progression, and treatment, are therefore likely to recruit and enroll participants with relatively less socioeconomic power—perhaps due to convenience and cost, but also as a function of the distribution of disease, as well as the separately impoverishing effects of disease. Biomedical research with healthy, compensated volunteers may also draw poorer subjects willing to trade off their time, convenience, and (sometimes) safety for pay. Multiple studies have shown how participants may approach research as a form of employment,¹⁵ but compensation for research participation is held down to avoid problems of unduly influencing poor individuals to take research risks.¹⁶ Some have also argued that current practices of payment for research participation exploit an “underclass” of healthy volunteers compensated to test experimental medications in Phase I trials—the first (and riskiest) human tests of new drugs.¹⁷

Given these dynamics, when a dispute arises due to perceived injury or misconduct experienced by research participants, research institutions often hold a comparative advantage in sophistication, access to human and financial resources, and access to the legal system—compared to both participants and investigators. Institutions are also repeat players, compared to participants who may only take part in one or a few studies, and they may experience a comparative advantage due to expertise or relationships strengthened by multiple experiences. These comparative disadvantages for research participants present intertwining ethical and procedural questions when designing a dispute resolution system.

¹³ See, e.g., HARRIET WASHINGTON, *MEDICAL APARTHEID* (2014).

¹⁴ Sandro Galea et al., *Estimated Deaths Attributable to Social Factors in the United States*, 101 *AM. J. PUB. HEALTH* 1456 (2011); Paula Braverman & Laura Gottlieb, *The Social Determinants of Health: It's Time to Consider the Causes of the Causes*, 129 *PUB. HEALTH REPS.* 19 (2014); Steven H. Woolf & Paula Braverman, *Where Health Disparities Begin: The Role of Social and Economic Determinants – and Why Current Policies May Make Matters Worse*, 30 *HEALTH AFF.* 1852 (2011).

¹⁵ Carl Elliott & Roberto Abadie, *Exploiting a Research Underclass in Phase I Clinical Trials*, 1 *N ENG. J. MED.* 2316 (2008); ROBERTO ABADIE, *THE PROFESSIONAL GUINEA PIG: BIG PHARMA AND THE RISKY WORLD OF HUMAN SUBJECTS* (2010).

¹⁶ See Emily A. Largent and Holly Fernandez Lynch, *Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward*, 17 *YALE J. HEALTH POL'Y L. & ETHICS* 61 (2017); William M. Sage, *Paying Research Subjects: The U.S. Example*, in *ESSAIS CLINIQUES, QUELLS RISQUES?* 137 (A. Laude & D. Tabuteau, eds., 2007).

¹⁷ Elliott & Abadie, *supra* note 15; ABADIE, *supra* note 1515.

Researchers' interests are also at stake. When resolving disputes between participants and investigators, IRBs also have the task of balancing investigators' interests, which may at times diverge from the interests of the institution. For example, complaints alleging researcher misconduct, protocol deviations, or harassment may expose institutions to liability, but the stakes are high for the investigators themselves, who could face termination of their research protocol, their entire research program, or their employment. These situations can be precarious for subjects, investigators, and research institutions alike, and IRBs faced with the management (or even merely the initial intake) of these disputes must navigate these conflicts. Although researchers do not have the historic structural disadvantage of research participants—they are well-educated and at times legally sophisticated parties—researchers' experience of fair process is essential for the long-term function of these dispute resolution programs.

The goal of this Article is to provide the first description of IDR processes used by research institutions to address injuries and other grievances brought by participants in human subjects research. My in-depth interviews with informants at federally funded U.S. hospitals and universities have revealed that institutions maintain permanent, highly flexible IDR processes in which the IRB manages initial complaint intake, complaint investigation, involvement of institutional and sometimes external stakeholders, identification of potential remedies, decisions that are binding for research protocols, and enforcement of those decisions. These processes accommodate not only physical injuries, but also non-justiciable claims and concerns brought by people who are not (or not yet) enrolled in research protocols. The highly flexible and sometimes unwritten nature of these processes allows IRBs substantial discretion in the dispute resolution process, and IRBs use this discretion to maximize participation and voice for subjects, investigators, and other community stakeholders. Informants often described the goals of their IDR systems with reference to Belmont Report principles, including respect for autonomy and justice. IRB informants also noted their federal mandate to protect research subjects, and discussed research subjects with attention to potential vulnerability or disparities in resources and sophistication. This case study provides a useful demonstration more generally of how procedural flexibility in ADR can serve participation and legitimacy interests for complainants.

Despite the wide breadth of these IDR systems, however, this study identified recurring shortcomings of IDR processes for research-related disputes. This Article will consider three shortcomings in particular. First, as a procedural matter, the design of these systems uniformly omitted consultation with participants, or with non-institutional personnel who could represent participant interests. IRBs typically began with informal office practices for handling subject complaints, and then codified these practices into more formal systems when pursuing institutional accreditation under the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which requires a written policy on complaint resolution. Design features mitigate the problem of non-consultation: for example, built-in procedural flexibility allowed individual subjects some control over the process at the time of their complaint, IRB personnel who designed the systems might be said to represent participant interests already, and some IRBs involved trusted local authorities at the moment when disputes arose. But the lack of participant consultation at the time of system design was a missed opportunity to establish systems that would be accessible and trusted by participants.

Second, informants consistently believed that uptake by subjects was low, compared to hypothesized rates of injuries and other complaints. There are numerous explanations for a lower rate of uptake, including a low frequency of grievances, low salience or importance of grievances to research subjects, and high effectiveness of initial researcher responses (i.e., before participants decide to contact the IRB). But a low rate of uptake may also indicate deficiencies in the process. Some informants suggested that participants may be suspicious of IRB-maintained systems as non-neutral processes, while many suggested that participants are unaware that the institution is willing to remedy research-related complaints. Based on my study of the available processes, as well as typical disclosures and informed consent forms, another possibility is that procedural flexibility *itself* can complicate efforts to make such processes predictable, and to make procedural information available in advance. The flexibility for IRBs to determine procedures on a case-by-case basis may undermine the predictability and legitimacy of the process for *prospective* claimants (those considering complaining), even though the IRB may seek to use that flexibility in ways that benefit *actual* claimants who are using the process.

Third, these interviews also indicated significant ambiguity regarding the capacity of IRBs to undertake dispute resolution, with respect to both neutrality and skills. Although these bodies must protect research participants, research-related disputes systems ask the same personnel to act neutrally toward investigators and the institution, which may be concerned about legal exposure, public image, and sustainability of relationships with participant communities. IRB personnel are also colleagues with ongoing relationships with investigators, and informants acknowledged that the stakes of some complaints for investigators are high. Sensitivity to investigator interests may account for the common practice of allowing investigators to appeal IRB decisions, while participants are not generally given notice of an appeal opportunity. In many ways, the use of IRBs to resolve research-related disputes is efficient: it takes advantage of existing scientific expertise; the federal regulations already give these bodies enforceable control over research protocols, which is often needed for durable remedies; and IRBs' central mandate to safeguard participant well-being may provide a much-needed thumb on the scale in favor of participant interests. But some informants in this study noted difficulties in maintaining impartiality in the face of institutional pressure and investigator pushback, and IRB personnel often noted their lack of training in dispute resolution, mediation, or investigations. Managing research-related disputes can also tax IRBs' human resources, especially given the range of potential procedures that may be necessary to fully address a complex dispute.

Based on these findings, this Article offers several recommendations to improve the design of IDR systems for resolving research-related complaints. Because participants are party to all such disputes, and particularly in light of the power disparities between research institutions and participants, institutions should involve participants themselves in the initial design or improvement of a dispute resolution system. Baseline data on the frequency of participant grievances is largely unavailable, particularly for complaints alleging intangible harm, and it is difficult to be certain that the low uptake of IDR systems is problematic. But in light of preliminary evidence that systems are underutilized, I suggest a greater emphasis on dispute resolution systems in the informed consent process, perhaps including procedural information and requiring a verbal discussion in addition to written informed consent, where practicable. Finally, although it may not be necessary to take these procedures out of the IRB, I suggest that institutions may consider providing

IRB personnel with training in dispute resolution, conflict management, or mediation, as well as additional personnel for highly complex complaints. Furthermore, it may improve neutrality to provide for independent external review of IRBs' dispute decisions, which may be invoked by the participant, investigator, and IRB itself. It may be unwise to establish these as federal regulatory requirements, given the advantages of procedural flexibility in this context. But research institutions may in fact adopt these practices voluntarily, given the ethical and practical advantages of a functioning IDR program.

This Article proceeds in the following Parts. Part II will situate research-related disputes in the context of other ADR uses in healthcare settings, and then identify the sources of authority, ethical guidance, and regulatory flexibility for research institutions to design processes that address participant injuries and concerns. Part III presents the empirical study and a process-specific appraisal of institutional systems for research-related disputes. This section will note the multiple roles of the IRB throughout the IDR process, as well as IRBs' uses of procedural flexibility to serve what they perceive to be participants' interests. Part IV discusses informants' appraisal of these systems, followed by a more critical evaluation of strengths and weaknesses. Part V concludes by considering strategies for improving IDR in this context.

II. IDR FOR RESEARCH-RELATED DISPUTES

Despite a wide-ranging set of federal regulations, federal laws, state laws, and professional requirements governing research with human subjects, there is a persistent gap in formal guidance for resolving disputes that arise in human subjects research. The federal regulations that govern most research in the United States are silent on this issue, as are federal and state laws and aspirational ethical guidance governing domestic and global research. This gap in regulation corresponds to a near-total absence of knowledge about the processes by which research-related injuries and disputes are resolved.¹⁸ Most scholarship in this area focuses on the problem of financial compensation for physical injuries that arise in the course of research.¹⁹ Although many such injuries are unavoidable risks of clinical research, some have provided a valid basis for litigation, including justiciable claims against institutions and individuals who conduct research, IRBs and institutional officials who oversee research, research sponsors, and manufacturers of products tested in clinical research protocols.²⁰ Institutions may seek to settle such claims quickly,²¹ but the IDR processes that may facilitate settlement are entirely unknown. Moreover, even when physical injuries are alleged, litigation is unavailable for several categories of claimant and injury, making alternative dispute resolution processes the only option for dispute resolution.²²

¹⁸ Kristen Underhill, *Legal and Ethical Values in the Resolution of Research-Related Disputes: How can IRBs Respond to Participant Complaints?*, 9 J. EMP. RES. HUM. RES. ETHICS 71 (2014).

¹⁹ Pike, *supra* note 5; Michelle M. Mello, David M. Studdert & Troyen A. Brennan, *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40 (2003); E. Haavi Morreim, *Clinical Trials Litigation: Practical Realities as Seen from the Trenches*, 12 ACCOUNTABILITY RES. 47 (2005); Carl Elliott, *Justice for Injured Research Subjects*, 367 N. ENG. J. MED. 6 (2012).

²⁰ Mello et al., *supra* note 19; David B. Resnick, *Liability for Institutional Review Boards: From Regulation to Litigation*, 25 J. LEGAL MED. 131 (2004).

²¹ Mello et al., *supra* note 19, at 43.

²² Here, I consider ADR to include institutional processes for compensating injuries through insurance, if the institution is one of the few that insures against research-related injuries. See Pike, *supra* note 5.

The scholarly focus on physical injuries has also obscured a much wider universe of potential grievances by research participants, including claims with more precarious footing in U.S. courts. These may include claims of dignitary or intangible harm, participant abandonment, inadequate informed consent, negligent protocol design, post-research access to drugs or devices, access to incidental research findings, or concerns about compensation, or complaints about the lack of privacy or confidentiality.²³ Where such claims have been unsuccessful in litigation, ADR processes are once again the only available forum for dispute resolution. The remainder of this Section will consider other uses of ADR in healthcare settings, available guidance for IRBs responding to research-related complaints, and predictable categories of disputes.

A. Uses of IDR in Healthcare

IDR programs are on the rise in healthcare settings, largely inspired by changes in the resolution of medical malpractice claims. These systems include communication-and-resolution programs for medical errors,²⁴ disclosure and apology programs for the proactive disclosure of errors,²⁵ and the use of ombudsmen or other internal complaint-handling processes for both justiciable and non-justiciable complaints in hospital settings.²⁶ Institutions are also experimenting with private or court-annexed medical malpractice arbitration.²⁷ Mandatory arbitration has been particularly controversial in the nursing home setting, and as of this writing, the Centers for Medicare and Medicaid Services has proposed a rule that would loosen requirements needed for nursing homes to impose binding arbitration agreements.²⁸ Licensing boards for physicians and nurses offer another forum for the resolution of complaints against individual providers, including complaints from patients and referrals from other authorities.²⁹ Because these are external, rather than IDR programs, however, they are less applicable to research-related disputes.)

IDR is also used outside the context of medical errors and patient complaints. Healthcare ethics committees have emerged as a method for managing disputes about

²³ See *infra*. Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941 (2005) [hereinafter Saver, *Medical Research*]; Richard S. Saver, *At the End of the Clinical Trial: Does Access to Investigational Technology End as Well?*, 31 W. NEW ENG. L. REV. 411 (2009) [hereinafter Saver, *At the End*]; Morreim, *supra* note 1919; Underhill, *supra* note 18.

²⁴ William M. Sage et al., *How Policy Makers Can Smooth the Way for Communication-and-Resolution Programs*, 33 HEALTH AFF. 11 (2014).

²⁵ Joanna C. Schwartz, *A Dose of Reality for Medical Malpractice Reform*, 88 N.Y.U. L. REV. 1224 (2013); Maria Pearlmutter, *Physician Apologies and General Admissions of Fault: Amending the Federal Rules of Evidence*, 72 OHIO ST. L.J. 687 (2011).

²⁶ Orna Rabinovich-Einy, *Escaping the Shadow of Malpractice Law*, 74 L. & Contemp. Probs. 241 (2011); Rabinovich-Einy, *supra* note 6; Orna Rabinovich-Einy, *Beyond IDR: Resolving Hospital Disputes and Healing Ailing Organizations through ITR*, 81 ST. JOHN'S L. REV. 173 (2007).

²⁷ Stephanie Smith & Janet Martinez, *Analytic Framework for Dispute Systems Design*, 14 HARV. NEGOT. L. REV. 123, 128 (2009) (reporting Kaiser case study); Matthew Parrott, *Is Compulsory Court-Annexed Medical Malpractice Arbitration Constitutional?*, 75 FORDHAM L. REV. 2685 (2007)

²⁸ CMS Issues Proposed Revision Requirements for Long-Term Care Facilities' Arbitration Agreements, June 5, 2017, available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-06-05.html>.

²⁹ Timothy S. Jost et al., *Consumers, Complaints, and Professional Discipline: A Look at Medical Licensure Boards*, 3 HEALTH MATRIX 309 (1993).

courses of treatment for patients, reconciling the interests of patients, families, and caregivers.³⁰ Bioethics mediation processes, including particularly the approach suggested by Nancy Dubler and Carol Liebman, integrates mediation skills into clinical ethics consultation, promoting shared decision-making and consensus in clinical conflicts.³¹ Outside clinical care, health insurers offer internal procedures for managing coverage disputes, with external review mandated by state law (in most states)³² and the Affordable Care Act.³³ Some disputes that arise in healthcare and health research settings are also those of large organizations more generally, including concerns about employment and discrimination, interpersonal conflicts, shared credit and workload, and organizational concerns. Susan Sturm and Howard Gadlin have discussed the National Institutes of Health's ombudsman program for handling these types of disputes, noting the interplay between individual-level and systemic analyses and solutions for organizational problems.³⁴

Aggregating these IDR processes raises questions about healthcare exceptionalism:³⁵ whether process values or goals should be differently weighted in healthcare settings because there are distinctive interests at stake. Procedural scholars have long enumerated the underlying purposes and values of procedural due process adjudication, and claims about the values served by process have extended from litigation and administrative adjudication to ADR and IDR.³⁶ The design of dispute resolution procedures are now widely acknowledged to serve not only accuracy,³⁷ but also other values, particularly given the impossibility of perfect accuracy in any system.³⁸ One such value is participation by claimants, either because participation is an intrinsic good,³⁹ or because it is instrumental⁴⁰

³⁰ Thaddeus Mason Pope, *Multi-Institutional Healthcare Ethics Committees: The Procedurally Fair Internal Dispute Resolution Mechanism?*, 31 CAMPBELL L. REV. 257 (2009).

³¹ NANCY NEVELOFF DUBLER & CAROL B. LIEBMAN, *BIOETHICS MEDIATION: A GUIDE TO SHAPING SHARED SOLUTIONS* (2011).

³² Nan Hunter, *Managed Process, Due Care: Structures of Accountability in Health Care*, 6 YALE J. HEALTH POL'Y, L. & ETHICS 93 (2006).

³³ Patient Protection and Affordable Care Act, Pub. L. 111-148 (2010); Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act, 75 FR 43329, July 23, 2010 (codified at 26 C.F.R. § 54, 26 C.F.R. § 602, 29 C.F.R. § 2590, 45 § C.F.R. 147 (2017)); Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes 76 F.R. 37207, June 22, 2011, codified at 26 C.F.R. § 54; 29 C.F.R. § 2590, and 45 C.F.R. § 147 (2017). The ACA mandates external review mechanisms for coverage determinations in group health plans and individual plans in the federal and state marketplaces.

³⁴ Susan Sturm & Howard Gadlin, *Conflict Resolution and Systemic Change*, 2007 J. Disp. Resolution 1, 2 (2007).

³⁵ Hunter, *supra* note 32.

³⁶ See, e.g., Rebecca Hollander-Blumoff, *The Psychology of Procedural Justice in the Federal Courts*, 63 HASTINGS L.J. 127 (2011); Rebecca Hollander-Blumoff & Tom R. Tyler, *Procedural Justice and the Rule of Law: Fostering Legitimacy in Alternative Dispute Resolution*, 2011 J. DISP. RESOL. 1 (2011).

³⁷ Martin H. Redish & Lawrence C. Marshall, *Adjudicatory Independence and the Values of Procedural Due Process*, 95 YALE L.J. 455 (1986); Lawrence B. Solum, *Procedural Justice*, 78 S. Cal. L. Rev. 181 (2004).

³⁸ Solum, *supra* note 37, at 185. Laurens Walker, *Avoiding Surprise from Federal Civil Rule Making: The Role of Economic Analysis*, 23 J. LEGAL STUD. 569 (1994).

³⁹ See, e.g., JERRY MASHAW, *DUE PROCESS IN THE ADMINISTRATIVE STATE* (1985), at 177.

⁴⁰ See Matthew J.B. Lawrence, *Procedural Triage*, 84 FORDHAM L. REV. 79 (2015) (describing the importance of participation with respect to psychological, dignitary, and legitimacy theories).

in producing a psychological experience of fairness,⁴¹ promoting dignified treatment,⁴² or conferring legitimacy on decisions.⁴³ Other values may include system legitimacy (including “the appearance of fairness”⁴⁴), predictability,⁴⁵ equality of parties,⁴⁶ accountability of parties,⁴⁷ “revelation” and explanation of the events that led to the claim,⁴⁸ and respect for dignity and privacy.⁴⁹

Many (although not all) grievances arising in healthcare settings present a unique combination of physical or mental vulnerability, information asymmetry, emotional weight, socioeconomic disparity, cultural difference, urgency, and visceral need, particularly conflicts involving individual patients and healthcare providers.⁵⁰ In this context, process values such as revelation, equality, accountability, participation, and dignity take on greater salience; IDR innovations such as disclosure-and-apology, communication-and-resolution, and bioethics mediation express these values clearly. Because research with human subjects presents many of the same contextual features, we may expect similar process values to have a high priority in IDR for research-related complaints.

The legitimacy of not only the IDR process, but also the larger system of healthcare services is also an important priority for inherent and instrumental reasons. Medical mistrust is a formidable barrier to accessing care⁵¹ and promoting quality in care delivery⁵² and perceived mistreatment in medical contexts can foster litigation and violence.⁵³ Both undermine the core goals of healthcare institutions, many of which are nonprofit corporations principally engaged in patient care. Given the goals of institutional legitimacy, such institutions may be more receptive to addressing non-justiciable disputes based on interests rather than legal rights.⁵⁴ IDR is the only process option for these types of disputes. Many IDR processes in healthcare settings were established as alternatives to public adjudication of justiciable claims, such as medical malpractice claims sounding in tort or coverage disputes sounding in contract. But IDR innovations in health law also

⁴¹ Louis Kaplow & Steven Shavell, *Fairness versus Welfare* (2002); see also Lawrence, *supra* note 40, at 92.

⁴² Jerry L. Mashaw, *Administrative Due Process: the Quest for a Dignitary Theory*, 61 BOS. U.L. REV. 885, 886 (1981). MASHAW, *supra* note 39.

⁴³ Solum, *supra* note 37, also cited by Lawrence, *supra* note 40.

⁴⁴ Redish & Marshall, *supra* note 37.

⁴⁵ Mashaw, *supra* note 39 at 175-76, also quoted by Redish & Marshall, *supra* note 37.

⁴⁶ Redish & Marshall, *supra* note 37, at __; MASHAW, *supra* note 39 at 171

⁴⁷ See Galanter, *supra* note 12. This is particularly problematic for some forms of ADR, such as internal dispute resolution, whereby one party designs the procedural rules and provides the forum. See Lauren B. Edelman & Mark C. Suchman, *When the Haves Hold Court: Speculations on the Organizational Internalization of Law*, 33 L. & SOC’Y REV. 941 (1999).

⁴⁸ Redish & Marshall, *supra* note 37 (quoting Michelman); Hunter, *supra* note 32.

⁴⁹ Mashaw’s theory considers dignity the overarching underlying value served by equality, predictability, participation, and privacy. MASHAW, *supra* note 39, at 172-82.

⁵⁰ Hunter, *supra* note 32.

⁵¹ Thomas A. LaVeist, Lydia A. Isaac, & Karen Patricia Williams, *Mistrust of Health Care Organizations is Associated with Underutilization of Health Services*, 44 HEALTH SERVICES REV. 2093 (2009); Kristen Underhill et al., *A Qualitative Study of Medical Mistrust, Perceived Discrimination, and Risk Behavior Disclosure to Clinicians by U.S. Male Sex Workers and Other Men Who Have Sex with Men*, 92 J. URBAN HEALTH 667 (2014).

⁵² Rabinovich-Einy, *supra* note 6, at __; see also Mark A. Hall et al., *Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter?*, 79 MILBANK Q. 613 (2001).

⁵³ *Id.*, at 68, 78.

⁵⁴ *Id.*

extend to disputes that would not support litigation in public courts. Bioethics mediation, healthcare ethics committees, internal complaint-handling mechanisms and hotlines at hospitals, and fora such as ombudsman programs in large health-related organizations all address both justiciable and non-justiciable claims. The availability of fora for these disputes promotes not only participation values, but also legitimacy of the care system more generally. These themes are all present in the context of research-related disputes, to which we now turn.

B. Authority and Guidance for IDR in Research Settings

Although the institutions that conduct human subjects research are subject to complex and overlapping federal and state laws, as well as informal ethics guidance and the requirements of professional self-governance and accreditation, the resolution of research-related disputes is an almost entirely unregulated space. This Section will describe the authority and existing guidance for research institutions addressing participant complaints.

The regulatory provisions governing research with human subjects include 45 C.F.R. § 46 (for research at institutions receiving federal funding through most agencies and departments) and 21 C.F.R. § 50 and 21 C.F.R. § 56 (for research that will be submitted as part of an application for FDA approval of a new drug or device). These regulations grant IRBs (which may be internal or external to research institutions) the authority to approve and monitor research protocols on an ongoing basis. As part of this authority, IRBs are empowered to withdraw approval, suspend, or terminate studies.⁵⁵ This authority entails stoppage or modification of a protocol in response to a complaint or injury. Although IRBs have authority over research protocols, however, the federal regulations are silent on the processes by which participant grievances should be resolved. The Common Rule refers to these processes only directly: as part of informed consent, participants must receive contact information for a party who can provide “answers to pertinent questions about the research and research subjects’ rights, and . . . in the event of a research-related injury to the subject.”⁵⁶ Institutions almost universally satisfy this requirement by providing participants with the contact information of the IRB, although the regulations do not specify that the IRB is the correct or only resource for questions about rights and injuries.⁵⁷ Dispute resolution receives no further attention in the recent revisions to the Common Rule.⁵⁸

The Office of Human Research Protections (OHRP) within the Department of Health and Human Services, which is tasked with enforcing the Common Rule,⁵⁹ has issued formal guidance to assist institutions in their oversight of human subjects research. These guidance documents, however, address only subject concerns that fall into the categories of “adverse events” or “unanticipated problem involving risks to subjects or others.”⁶⁰ Adverse events are narrowly defined as “untoward or unfavorable medical occurrence[s] . . . temporarily associated with the subject’s participation in the research,” while unexpected

⁵⁵ 45 C.F.R. § 46.109.

⁵⁶ 45 C.F.R. § 46.116(a)(7); 21 C.F.R. § 50.25(a)(7).

⁵⁷ Underhill, *supra* note 18.

⁵⁸ ANPRM

⁵⁹ Sharona Hoffman, *Continued Concern: Human Subject Protection, the Institutional Review Board, and Continuing Review*, 68 TENN. L. REV. 725 (2001)

⁶⁰ 45 C.F.R. § 103(b)(5).

problems are incidents that are “unexpected . . . related or possibly related to participation in the research . . . [and] suggest that the research places subjects or others at a greater risk of harm . . . than was previously known or recognized.”⁶¹ Even within these categories, the focus of OHRP guidance is on how institutions should report the events and correct the research protocol—rather than providing mechanisms for addressing the harm experienced by the individual subjects. OHRP does not direct IRBs to enact a complaint resolution policy separate from these procedures.⁶²

Many states also govern human research by statute or regulation, but like the federal regulations, these are typically silent on the mechanisms by which institutions resolve disputes with individual participants. State statutes governing research in California, for example, require that participants in medical research receive “the name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.”⁶³ “Impartial third party,” however, is not defined, nor is the procedure by which this third party should resolve the dispute.⁶⁴ New York state law requires that research protocols falling outside federal regulatory requirements be reviewed by a “human research review committee”⁶⁵ and that researchers secure informed consent from subjects,⁶⁶ but does not address the resolution of research-related complaints.

Apart from federal and state law, a quasi-binding requirement for institutions to address research-related complaints arises from professional accreditation. Modern IRBs are often part of broader “human research protection programs” in research institutions, which encompass functions such as protocol review and approval, research ethics instruction for investigators and research staff, development of institutional policies, ensuring compliance of research protocols with state law, monitoring conflicts of interest in research, and managing unanticipated problems and adverse events. Human research protection programs can apply for accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which has two requirements relevant to the management of research-related disputes. First, researchers and staff must “have a process to address participants’ concerns, complaints, and requests for information.”⁶⁷ Second, organizations as a whole must “ha[ve] and follo[w] written policies and procedures that establish a safe, confidential, and reliable channel for current, perspective, or past research participants . . . that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the

⁶¹ OHRP, Unanticipated Problems Involving Risks & Adverse Events Guidance (2007).

⁶² The self-assessment tool for OHRP’s Quality Assessment Program asks whether the IRB operates a “hot line or 800 number for potential or enrolled participants to file complaints or direct questions regarding human subjects protection issues,” as well as whether the IRB provides an advocacy program or ombudsman for participants, but no additional guidance appears to be available in this area. Office of Human Research Protections. (2013). OHRP QA Self Assessment Tool Retrieved March 5, 2013, from http://www.hhs.gov/ohrp/education/qip/ohrp_ded_qatool.html

⁶³ Cal. Health & Safety Code § 24173(c)(10)

⁶⁴ Research with prisoners may be an exceptional case. California also requires that “provisions have been made for compensating research related injury” occurring to prisoners enrolled in research, and that the Department of Corrections provide a process for hearing grievances occurring in research. Cal. Penal Code § 3515(d), 3518.

⁶⁵ N.Y. Pub. Health § 2444

⁶⁶ N.Y. Pub. Health § 2442

⁶⁷ AAHRPP, AAHRPP Accreditation Standards, Oct. 1, 2009.

specific research protocol or plan.”⁶⁸ This duty is not located with the IRB; for example, organizations could fulfill the requirements using an ombudsman or research subject advocate. AAHRPP has set no requirements for structure of these processes, but simply requires that they exist, and implies that they should handle all types of concerns—including those that are not justiciable in public courts.⁶⁹

Aspirational ethics documents provide “soft law” principles that plausibly imply that researchers and research institutions have a duty to address the full range of participant complaints.⁷⁰ As noted above, there is a vast array of ethical guidance documents in medical research, including the Belmont Report, the Nuremberg Code, the CIOMS guidelines, the WMA Declaration of Helsinki, and others. These offer additional values that might be relevant to dispute systems design here, but no specific procedural guidance. On the basis of the Belmont report, for example, the design of a dispute resolution system in this field might seek to promote participant autonomy, beneficence, non-maleficence, and justice defined as equitable access to the benefits and burdens of research.⁷¹ But these broad norms leave wide latitude for procedures that attempt to address grievances arising in the course of research.

In some ways, this flexibility is typical of research oversight more generally, in which the regulation of research is broadly decentralized and delegated to IRBs as what Laura Stark has called “declarative groups—their act of deeming a practice acceptable would make it so.”⁷² The federal regulations do not dictate the outcome of any particular protocol, but rather leave these decisions up to IRBs themselves, even permitting IRBs to waive informed consent requirements entirely under certain conditions.⁷³ IRBs also retain procedural flexibility in the format of their deliberations, and institutional practices on IRB membership and deliberation vary; variation across IRBs is reinforced by consulting prior decisions within the institution as precedent.⁷⁴

D. Gaps in Understanding Research-Related Disputes

Despite near-total freedom for the design of IDR processes in this field, the actual dispute resolution practices of research institutions operating in this regulatory gap have gone entirely unexamined. Drawing on the literatures above, many similar process values will be important for the resolution of disputes in this field. These include the values of participation, legitimacy (including legitimacy of the process and broader legitimacy of

⁶⁸ Id.

⁶⁹ IRB professionals can pursue individual certification through the Certified IRB Professional program (CIP) run by the Public Responsible in Medicine & Research (PRIM&R) organization. This program, however, does not provide specific training on the management of research-related disputes. PRIM&R, CIP Body of Knowledge/Content Outline, <http://www.primr.org/WorkArea/DownloadAsset.aspx?id=9643>.

⁷⁰ Underhill, *supra* note 18.

⁷¹ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education & Welfare, *The Belmont Report* (1979).

⁷² Laura Stark, *Victims in Our Own Minds? IRBs in Myth and Practice*, 41 L. & Soc’y Rev. 777 (2007) [hereinafter Stark, *Victims*]; LAURA STARK, BEHIND CLOSED DOORS: IRBS AND THE MAKING OF ETHICAL RESEARCH 164 (2012); Laura Stark and Jeremy A. Greene, *Clinical Trials, Healthy Controls, and the Birth of the IRB*, 375 N. ENG. J. MED. 1013 (2016).

⁷³ 45 C.F.R. § 46.116(d).

⁷⁴ Stark, *Victims*, *supra* note 72; STARK, *supra* note 72, at 165.

scientific research), predictability for potential and actual disputants, equality and accountability in a context where research subjects are less powerful than research institutions, revelation for subjects interacting with a highly specialized field of knowledge, and dignity and privacy interests for all disputants. Moreover, dispute systems for resolving research-related disputes likely have similar proximate goals to other ADR processes, such as efficiency, durability, and party satisfaction.

I have previously noted the range of grievances that may arise in human subjects research.⁷⁵ Most previous scholarship in this area has focused on physical injuries that are inherent risks of research,⁷⁶ or that arise from negligence in protocol design, approval, or implementation.⁷⁷ Litigants bringing tort claims against research institutions have alleged wrongs including negligent protocol design or implementation, lack of informed consent, emotional distress, fraud, misrepresentation, battery, medical malpractice, products liability claims, privacy violations, breach of contract, wrongful death, state law violations, conspiracy, participant abandonment, unjust enrichment, and IRB misconduct including negligent study approval and oversight.⁷⁸ Additional claims may include failure to disclose individual study results, premature study termination, and withholding or denying access to treatments after the study has concluded.⁷⁹ Complaints made outside litigation have included allegations of noncompliance with protocols, delayed payments, unwanted requests for study participation, perceived HIPAA violations,⁸⁰ and lack of confidentiality.⁸¹ Research on the therapeutic and preventive misconceptions suggests that many participants do not fully understand protocols at the time of informed consent,⁸² which can generate complaints later. Many of the concerns visible in healthcare settings more generally—such as perceived rudeness, long wait times, miscommunications, and other “small-scale disputes”⁸³—are almost certainly present in the research context as well. Other complaints may have more in common with workplace grievances; many participants in non-therapeutic research see their participation as paid work, and view study terms as conditions of employment.⁸⁴ There has been no systematic study, however, of how institutions may seek to resolve the universe of participant concerns.

For many if not most of these claims, IDR processes are the only available venue for dispute resolution. Litigation is a poor fit for many of these disputes. Some of the claims noted above have been rejected by courts (e.g., claims to post-trial access⁸⁵) or do not allege

⁷⁵ Underhill, *supra* note 18.

⁷⁶ Pike, *supra* note 5.

⁷⁷ Mello et al., *supra* note 19.

⁷⁸ Underhill, *supra* note 18 (citing additional sources), Mello et al., *supra* note 19; Saver, *At the End*, *supra* note 23; Saver, *Medical Research*, *supra* note 23; Morreim, *supra* note 19.

⁷⁹ Gordon 2009, Saver, *Medical Research*, *supra* note 23

⁸⁰ HIPAA does not provide for a private right of action, but state courts may rely on HIPAA for setting the standard of care in tort actions for privacy violations. *Byrne v. Avery Ctr. for Obstetrics & Gynecology, P.C.*, 314 Conn. 433 (2014) https://apps.americanbar.org/litigation/litigationnews/top_stories/030215-hipaa-disclosure.html

⁸¹ Underhill, *supra* note 18 (citing sources).

⁸² Flory & Emanuel, *supra* note 8

⁸³ Rabinovich-Einy, *supra* note 6.

⁸⁴ Peter Davidson & Kimberly Page, *Research Participation as Work: Comparing the Perspectives of Researchers and Economically Marginalized Populations*, 102 AM. J. PUB. HEALTH 1254 (2012). The journal GUINEA PIG ZERO—an “occupational jobzine” for study participants—is emblematic of this view. <http://www.guineapigzero.com/>. See also sources cited *infra* n. 88.

⁸⁵ Saver, *At the End*, *supra* note 23.

legal violations (e.g., unwanted requests for study participation). Litigation is also legally or practically unavailable for some categories of research subjects. As Elizabeth Pike has pointed out, international participants may be barred from recovery due to the Federal Tort Claims Act and the Alien Tort Statute,⁸⁶ and US participants in federally conducted research may find their claims precluded due to sovereign immunity and the discretionary function exception to the Federal Tort Claims Act. Litigation has a number of drawbacks in the research context as well, including high costs that may raise the costs of research and lead IRBs to make excessively conservative decisions about study approval.⁸⁷

The literature on research-related disputes sheds little light on IDR options. Although some institutions provide no-fault compensation programs for research-related injuries, such programs are rare,⁸⁸ and we know little about the processes or process values they employ. Several protocols have set up study-specific ADR (not necessarily IDR) processes; interestingly, the two published papers on these processes are in HIV/AIDS research, reflecting the history of participant advocacy and community-based research.⁸⁹ Both programs resembled arbitration. In one program, a series of HIV vaccine trials in India created a three-person arbitration board to handle all grievances.⁹⁰ The other program was an informal arbitration system established for a consortium of AIDS treatment trials and was established to promote participants' "right to be treated with dignity"; participants could have their complaints represented by a social worker before a study panel, with the option to appeal the panel decision to the IRB.⁹¹

Only one published paper has described institutional practices for complaint resolution, published by IRB professionals at the Baylor College of Medicine.⁹² The Baylor system provides for an "iterative process that seeks to identify the truth about research-related complaints through fact-finding efforts."⁹³ As understood by this IRB, due process requires objectivity and the opportunity for all parties "to speak to the 'truth' as they perceive it."⁹⁴ Procedural elements include the requirement of a written complaint, IRB classification of the complaint as noncompliance or scientific misconduct, notification of a compliance assessment team and the principal investigator, a formal audit of study materials and "fact-finding" through interviewing relevant parties, review of factual findings by an IRB subcommittee, a face-to-face "hearing" involving the investigator and IRB subcommittee (but not the subject), full IRB deliberation and a preliminary decision imposing corrective actions or sanctions on the investigator, an option for the investigator to appeal the decision, and a final decision letter by the full IRB setting forth factual

⁸⁶ Pike, *supra* note 5; see also Sarah Gantz, *Judge Dismisses \$1 Billion Guatemalan Syphilis Experiment Case against Hopkins, Others*, BALTIMORE SUN, Sept. 9, 2016; *Estate of Alvarez v. Johns Hopkins Univ.*, 205 F. Supp. 3d 681 (D. Md. 2016).

⁸⁷ Mello et al., *supra* note 19; Underhill, *supra* note 18.

⁸⁸ Pike, *supra* note 5; Carl Elliott, *Justice for Injured Research Subjects*, 367 N. ENG. J. MED. 6 (2012); Lewin Group.

⁸⁹ Underhill, *supra* note 18.

⁹⁰ J.L. Excler et al., *Preparedness for AIDS Vaccine Trials in India*, 127 INDIAN J. MED. RES. 531 (2008).

⁹¹ Lisa E. Cox & Thomas M. Kerkering, *Grievance Procedures as Assurance for the HIV-Infected Clinical Trial Participant*, 1993 AIDS PATIENT CARE 20 (1993).

⁹² Kathleen J. Motil, Janet Allen, and Allison Taylor, *When a Research Subject Calls with a Complaint, What Will the Institutional Review Board Do?*, 26 IRB: ETHICS & HUMAN RESEARCH 9 (2004).

⁹³ *Id.*, at 13.

⁹⁴ *Id.*, at 9.

determinations and a binding corrective action plan. This arbitration-like process appears to prioritize accuracy and investigator voice, but says little about voice or remedy for the individual participant.

IDR has structural limitations in this context, particularly when the ADR process are maintained by institutions themselves. IRBs who maintain ADR processes have divided loyalties to their institutions, their colleagues, and the participants they are tasked with protecting, and IRB administrators may be concerned about their own liability in the event of litigation.⁹⁵ Financial incentives for researchers and institutions may encourage unethical behavior in both the oversight and implementation of research protocols.⁹⁶ And like all IDR programs, this context raises concerns about privatizing legal norms, transmuting rights-based claims into organizational issues, providing a highly unequal forum, and deterring publicly useful litigation.⁹⁷ But where IDR may be the only practicable option for resolving many of these disputes, it is important to interrogate the process choices that institutions have already made.

III. AN EMPIRICAL STUDY OF IDR FOR RESEARCH-RELATED DISPUTES

No previous research has examined the role of IDR in the resolution of research-related disputes. This Part will introduce the study methods, followed by results describing the frequency and nature of complaints, process options, uses of procedural flexibility, and informants' appraisal of their processes. Throughout, I will use "informants" to refer to individuals who participated in my interviews, and "subjects" or "participants" to refer to individuals who lodge (or may lodge) complaints with their IRBs. Where I have quoted informants directly, I have selected quotes that are most striking or most typical of responses across the full set of informants.

A. Methods

The goal of this empirical study was to understand the structure and animating procedural values of ADR processes that research institutions use to manage disputes involving human subjects. This Part presents the result of in-depth, semi-structured qualitative interviews with human research protections program officers at 30 hospitals and academic institutions throughout the US. All procedures were approved by the Yale Human Subjects Committee and advised by an expert panel of 6 scholars and IRB professionals. Data were protected by a Certificate of Confidentiality (COC) from NIH, which aims to facilitate research on sensitive topics by shielding individual participant data from subpoena.⁹⁸

The population of interest for this study was IRB chairs, directors, and other designated IRB personnel who have discretion in responding to complaints; all individuals

⁹⁵ Mello et al., *supra* note 19.

⁹⁶ Carl Elliott, *The University of Minnesota's Medical Research Mess*, *The N.Y. Times*, May 26, 2015, http://www.nytimes.com/2015/05/26/opinion/the-university-of-minnesotas-medical-research-mess.html?ref=opinion&_r=0

⁹⁷ See, e.g., Edelman & Suchman, *supra* note 47.

⁹⁸ Leslie E. Wolf et al., *Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice*, 43 J.L. MED. & ETHICS 594 (2015).

in the study had at least 1 year of experience reviewing human subjects protocols and had discretion in managing institutional responses to participant complaints. I interviewed one person per institution, with the exception of one institution, where I ran a joint interview with two IRB officers. Twenty-six of the 31 informants were chairs or directors of their IRBs; the others were managers or administrative chairs.

The unit of analysis for this study was the institution; I included IRBs that reviewed protocols for a hospital or academic institution, were located in the US and subject to US federal regulation, and had an OHRP-approved federal-wide assurance number.⁹⁹ A majority of eligible institutions¹⁰⁰ were academic institutions that encompassed both medical and nonmedical schools; I oversampled hospitals and universities lacking medical schools to ensure adequate data from these types of institution. The final sample included 20 universities with medical schools, 4 universities without medical schools (where almost all protocols were for social and behavioral research), and 6 hospitals.¹⁰¹ Institutions were located in all four US Census Bureau regions, and the sizes of their research portfolios ranged from 20 to more than 5,000 active protocols enrolling human subjects.

I did not include external or centralized (independent) IRBs; although centralized IRBs approve research protocols (and may experience liability for negligent approvals), they have different liabilities from institutions who receive funds from research sponsors, employ investigators and research staff, and provide material support and physical space

⁹⁹ Although institutions have procedural freedom to have complaints resolved outside the IRB, common practice is for this to be a core IRB function, and I thought IRBs would be aware of dispute resolution practices even if they occurred outside the IRB office.

¹⁰⁰ Because this study was funded through the Fordham HIV Prevention Research Ethics Training Institute, a second part of the interviews specifically considered management of disputes arising in biomedical HIV prevention research. In order to fulfill this part of the study, I further limited the sample to institutions that had received funding from any source within the previous 5 years to conduct social science research or clinical research on biomedical HIV prevention. I identified eligible institutions by searching all active protocols in the NIH RePORTER database as of May 2013, clinicaltrials.gov, and consulting trials networks for biomedical HIV prevention research. One hundred and sixteen unique institutions were eligible for inclusion. I used a computer-generated random number sequence to select simple random samples of ten institutions at a time for recruitment. I approached 73 institutions in order to secure the sample of 30 included interviews; the other 43 institutions either did not respond (35) or declined (8) for reasons including busy schedules or lack of expertise handling participant complaints. This design introduces some inevitable weaknesses; for example, there may be some social desirability in responses, and participating institutions may have been more comfortable discussing their procedures—perhaps because they had better-defined procedures or fewer negative experiences with research-related disputes. These limitations are inherent in most qualitative research designs, but they are balanced in this study by the strength of a simple random sampling procedure among eligible studies, full data saturation on all themes of interest, and stratification of recruitment across three different types of institution.

¹⁰¹ This sample size is appropriate for the collection of nuanced, in-depth data that explores variation and meaning in experiences, and it allows for data saturation. See Janice M. Morse, *Determining Sample Size*, 10 *QUALITATIVE HEALTH RES.* 3 (2000); Janice M. Morse, *The Significance of Saturation*, 5 *QUALITATIVE HEALTH RES.* 147 (1995). Data saturation refers to having collected sufficiently rich data to understand the key relationships at stake in the study—that is, collecting data until no new themes emerge with additional interviews—and although no formal metrics of saturation exist, qualitative researchers monitor their findings throughout studies to ensure that they research saturation before concluding data collection. See Morse, *The Significance of Saturation*; see also *CONSTRUCTING GROUNDED THEORY: A PRACTICAL GUIDE THROUGH QUALITATIVE ANALYSIS* (Kathy Charmaz, ed. 2006). I monitored for data saturation throughout this work by completing and transcribing a debriefing after each interview, then rereading debriefing reports to identify new and recurring themes. The final sample enabled a thorough exploration of the themes of this paper.

for study activities. I also did not focus on private industries; although drug and device manufacturers conduct human subjects protocols, they also may have a somewhat different set of liabilities as manufacturers. They also often rely on centralized IRBs, or may subcontract trials to hospitals or clinics. Limiting the scope of this project to hospitals and universities provides a first cut at the question of how research institutions resolve complaints and injuries involving human subjects, and subsequent work should focus on other research settings.

Each interview lasted 60-90 minutes and focused on the types and frequency of complaints, experiences with litigation involving human subjects, the development and application of ADR procedures for resolving research-related disputes, the need for guidance or training to handle research-related disputes, and the principal values or priorities of the institutional ADR processes.¹⁰² I conducted and audio-recorded all interviews, then analyzed verbatim transcripts thematically using NVivo 11, which allows the application of a formal coding structure to qualitative data. I used an initial set of planned codes for data analysis, but added new themes as they emerged from the data.

Table 1 reports information on the individual informants, while Table 2 reports information about the institutions they represented.

B. Frequency and Types of Disputes

Despite a wide and colorful variety of complaints that encompassed injuries, noncompliance, human resources issues, unwanted recruitment efforts, and cultural concerns, the overall frequency of complaints was far lower than might be expected. This low frequency was surprising to many informants, who sought to explain low system uptake as not only a result of good research practices, but also a result of subjects' lack of understanding of their rights, interests, and dispute resolution options.

1. Uptake of the Process

At all but one institution, the IRBs were listed as the resources for participant complaints on patients' informed consent forms; the remaining institution provided participants with information for a patient relations office, which reported any "non-trivial" complaints back to the IRB. Institutions handled between 20 and 5000 protocols; the largest research programs were at universities that included medical schools, while hospitals and universities without medical schools had smaller research programs. Given the variety and commonplace nature of potential participant complaints noted above, the numbers of complaints received by IRBs were surprisingly low, at an average of approximately 5 complaints per year per thousand active protocols. This figure reflects several outliers with larger numbers of complaints; the median complaint frequency was 2 complaints per year, per thousand active protocols. Complaints were somewhat more frequent at universities with medical schools (median 2.4 per year per thousand protocols), compared to universities without medical schools (median 0.5) and hospitals (median 1.8).

¹⁰² Each individual participant provided informed consent to interviews, completed an interview by phone, and received \$100 for their time. To protect institutions that may be experiencing research-related litigation, informed consent used an anonymous verbal process, and all data were deidentified before analysis.

Several institutions noted temporary spikes in complaints linked to identifiable events (e.g., media coverage of a protocol using an emergency exception to informed consent), but the stable frequency of complaints was around 2-5 complaints per thousand protocols per year.¹⁰³ Complaints were not spilling over into litigation instead; approximately one third of the institutions had been involved in litigation involving research subjects or staff, but these incidents were far less frequent than the number of complaints received.

This Part will explore potential causes for the low frequency of complaints below. The low figures observed here align, however, with fields such as medical malpractice and complaints about healthcare professionals, in which “most people choose to ‘lump’ their grievance (i.e., put up with it or ignore it) or to avoid expressing it by ‘exiting’ (abandoning or limiting) the troublesome relationship. In the medical context . . . the vast majority of patients do not sue for negligently caused injuries . . . Studies of complaining and claiming behavior are, therefore, studies of atypical behavior.”¹⁰⁴

2. *Subject Matter of Complaints: Rights and Interests*

Despite this low uptake, when subjects *do* use the process, the subject matter of their complaints varies widely and encompasses both legally cognizable and non-justiciable claims. Complaints are typically brought by subjects themselves, or family members of participants who are minors, participants who have diminished capacity to consent, and participants who are ill or deceased. Study staff may also bring complaints as whistleblowers, particularly when complaints concern the conduct of principal investigators. I did not include here complaints from principal investigators about IRB actions; many institutions reported these, but because my focus is on research subject disputes, they were outside the focus of this study.

Most institutions reported that complaints about the speed and adequacy of participant compensation are most prevalent, particularly for participants enrolling in non-therapeutic protocols (who may be more interested in compensation, rather than receiving an experimental intervention). Other complaints include concerns about the availability and adequacy of the informed consent process (especially for non-English speakers, minors, or elderly participants); waivers of informed consent or HIPAA authorization; data privacy and confidentiality; the release of research reports or publications that did not protect participant confidentiality; disrespectful, nonresponsive, harassing, discriminatory, or dismissive treatment by research staff; staff noncompliance with study protocols; sexual harassment by research staff; dissatisfaction with emergency procedures for managing psychological events during research studies (e.g., threats of suicide); study requests for personal identifiers, especially Social Security numbers; unexpected, painful, or offensive study activities; requests for the return of biological samples; requests to discontinue participation; student concerns about the use of educational records; complaints about physical accessibility of study premises for individuals with disabilities; anger about premature study termination, where studies had been stopped by researchers, sponsors or

¹⁰³ This is lower than a 2011 AAHRPP study that reported an average of 7.9 complaints per year per thousand protocols, among 193 AAHRPP-accredited institutions. My study included institutions with and without AAHRPP accreditation; the average for AAHRPP-accredited institutions was 4.0 complaints per year per thousand protocols. AAHRPP, *Metrics on Human Research Protection Program Performance* (2011).

¹⁰⁴ Jost, *supra* note 29, at 314

the IRB; requests for access to individual study results or other records; concerns about future use of study samples or data; adverse social or legal consequences of participating in study procedures;¹⁰⁵ malfunctioning equipment or technology provided by a study; and cleanliness of study facilities. Complaints also include physical injuries, particularly where participants believe they had not received a timely and thorough response from the investigative team.

Almost all institutions reported additional complaints from individuals *not* enrolled in research protocols. These complaints include community objections to study advertising (e.g., concerns about how study posters depict LGBT individuals); concerns about study recruitment and consent processes where sensitive protocols have received media attention; frustration with being found ineligible for participation in a particular study (particularly for patients who want access to a therapeutic protocol), or being excluded from a study midway through due to noncompliance or changes in eligibility; complaints that studies are wasting money on answering trivial or obvious research questions; concerns about repeated requests for study participation after refusal; student concerns about pressure to participate in professors' research; complaints from community organizers about a mismatch between expected and actual research activities in the populations they represent; complaints about researchers' misuse of access to medical records databases; and concerns from patients who were angry that the IRB had not yet approved a research protocol that they perceived to be beneficial. Some particularly sensitive complaints from non-participants also included concerns about culture, reputation, or identity; for example, complaints alleged that research results would harm the reputation of a community or organization, or that researchers were making inappropriate use of biological samples to study a Native American community.

Numerous institutions had received complaints from individuals who had been identified and contacted as potential subjects on the basis of their medical records or a state registry (e.g., asked to be in a prostate cancer study because their medical records included a prostate cancer diagnosis), which did not fit their expectations of medical record privacy. Institutions who reported these complaints had almost universally enacted institutional policy changes barring investigators from cold-calling participants on the basis of their medical records.

C. Process Goals and Values

Despite the heterogeneity across institutions in location, type of institution, and size, there were remarkable similarities in how institutions viewed their proximate goals and underlying process values. This Section will discuss each in turn, noting similarities in how informants described their systems.

¹⁰⁵ For example, one protocol enrolled a sex worker in an HIV vaccine trial, which causes the body to produce HIV antibodies despite the absence of infection. These antibodies caused her to test positive in an HIV antibody test when she was later arrested for prostitution, which triggered mandatory name-based reporting to the state and possibly enhanced penalties for the prostitution offense.

1. Proximate Goals

Informants reflected on a number of institutional goals for their dispute resolution systems. These goals included system outputs that are separable (and often measurable) results of the process (e.g., participant satisfaction), as well as a common set of desirable procedural features (e.g., neutrality of the decision-maker, transparency).

Most informants noted that the IRB's institutional role is to protect subjects enrolled in research protocols; the quality of decisions depended on how well they fulfilled this substantive goal, in addition to complying with federal regulations and ethical guidance. For these institutions, complaints are a source of feedback for modifying risky protocols or practices, and the resolution process sometimes led to system-level changes to policies applying across the institution.¹⁰⁶ Subject and investigator satisfaction with the process—if not the outcome—is also a primary goal at all institutions, and informants often described “customer satisfaction” or a “consumer service” approach for subjects as an overriding emphasis. As expected, another salient goal of this process is to protect the institution itself from litigation and adverse media exposure, in part by satisfying individual subjects' concerns, but also by maintaining an active feedback loop that identifies systemic risks. IRBs noted that individual or repeated complaints can identify defects in institutional policies, providing opportunities for revision and reform. As one informant noted, “The most important thing is to ensure the patient is, feels comfortable in the resolution . . . I guess secondly would be to ensure that we've implemented whatever processes need to happen to ensure it doesn't happen again.” Or as another said, “[We have] more policy-type resolutions so that I can go back to [an] individual and say . . . the institution has now changed its policy in a way this will not happen again A quality resolution . . . is not just a quick band-aid fix, but more of a long-term, proactive [step].”

Like many ADR processes, these systems aim for efficiency, speed, and accuracy, in part assured by the procedural flexibility inherent in the system design.¹⁰⁷ Speed was often cited as a goal of complaint resolution, with multiple informants noting that lengthy complaint processes may foster escalation of the dispute, particularly if parties are not kept abreast of progress. Consistency was another procedural goal, often fostered by written or standardized procedures. Conserving financial and administrative costs, however, was not typically a priority, and the costs of the ADR process were viewed as small in comparison to the threat of litigation and reputational exposures for the institution. Informants reported willingness to devote considerable time and resources to complaints in the interests of accuracy and fairness, and the low number of complaints enabled IRBs to prioritize thoroughness over administrative costs. (“As far as time, manpower, and all of that is concerned, I think you have to spend what you have to spend in order to make it a fair process.”) Moreover, very few complainants sought financial compensation for their grievances, with the exception of participants with uncompensated injuries or complaints related to expected payment for study activities.

In order to fulfill these proximate goals, institutions sought to create processes with a number of ideal safeguards. These included an easily accessible forum; having a written procedure or having the same personnel respond to all complaints; a full opportunity for

¹⁰⁶ See Sturm & Gadlin, *supra* note 34.

¹⁰⁷ See *infra*, Section III.E.

subjects and investigators to provide their version of the facts, including in-person or phone meetings with the IRB; options for the subject to elect anonymity or choose not to pursue corrective action; an opportunity for parties to choose facilitated negotiation or mediation; an initial triage point that allows for emergency actions such as study suspension; transparency about the process and communication of the outcome to investigators and subjects; provision of a third-party neutral with the authority to issue decisions that bind the institution; consultation of all complaint stakeholders and institutional actors, including trusted members of the subject's community where relevant; privacy of deliberations and decisions by the third-party neutral; a thorough fact-finding process that consults all relevant parties; a written, reasoned decision; opportunities for the investigator to weigh in on the corrective action plan; and an option to appeal.

2. Values of the Process

Informants' beliefs about the underlying value of a complaint resolution process reflected many, if not all, of the process values described in Part II above. The value of participation resonated most deeply throughout the interviews, both as an instrumental value (necessary to reach a resolution, promote legitimacy, or defuse conflict) and as an inherent value (an independent good for subjects who exert their autonomy by complaining). Informants intuitively described some themes arising in the procedural justice literature, such as an "opportunity to be heard" (voice); the need to treat participants empathetically and respectfully (courtesy); the need to provide a forum that approximates a neutral third party (neutrality); and the need for the IRB to be trustworthy or receive buy-in from trusted community authorities (trust). Procedures that involve all possible stakeholders to a complaint also advance participation values, and may also increase the legitimacy of both the forum and the substantive decisions made by the IRBs.

Equality between the subject and investigator is a second value, given IRB's efforts to provide neutral decisions and full participation opportunities for both sides. Accountability of the investigator for wrongs was an important corollary to this principle; importantly, however, this accountability is one-sided. Although the IRBs can compel investigators to take corrective actions, they have neither the authority nor the desire to sanction subjects. Of course, a final IRB decision that is adverse to the subject forecloses other options, particularly for non-justiciable complaints. But subjects cannot be made worse off *ex post*. The focus of accountability was also on individual investigators rather than the institution more generally, save for physical injuries (which may be compensated by institutional funds) and complaints that specifically alleged misconduct elsewhere in the institution (e.g., negligent approval of protocols by the IRB itself).

Informants' focus on consistency and the need for procedural transparency with complainants and investigators suggested that predictability was an important goal. Informants did not, however, identify the need to provide procedural information to subjects *before* the act of bringing a complaint. Indeed, very little about the process was disclosed *ex ante*, in part because IRBs maintained so much procedural discretion that precise procedural details were not known in advance. As overseers of the informed consent process, IRBs are well acquainted with the problems of how best to disclose information to research subjects. The difficulties of obtaining informed consent are

notorious.¹⁰⁸ Limited time is available for obtaining informed consent; participants may already be overwhelmed with information about the details of the research protocol; and the informed consent process often fails to present information in an accessible way. Prior studies have consistently found deficiencies in informed consent. One review found that participants lacked adequate comprehension of the study in 29% of research protocols, and lacked comprehension of the risks of surgery in 36% of surgical research protocols.¹⁰⁹ Participants in only 44% of protocols knew that they could withdraw from the study.¹¹⁰ Studies worldwide have found similar results, showing that comprehension varies widely, and that randomization and placebo-controlled trials present particular stumbling blocks for comprehension.¹¹¹ When it is already difficult to present significant facts about the research protocol in an accessible way, researchers may be limited in their ability to disclose detailed procedural information about participants' dispute resolution options. Against this backdrop, informants in the present study generally had not questioned the current practice of disclosing IRBs' contact information without further details about the dispute resolution process.

Informants were less likely to describe privacy as an independent value, with the exception of privacy for investigators who experience disciplinary sanctions. Instead, procedures safeguarded privacy interests in an effort to promote participation values, particularly in the use of procedures to receive and manage complaints made by subjects who wished to stay anonymous or confidential. No informant described using a formal confidentiality or nondisclosure agreement during the process, but internal deliberations of the IRB were wholly confidential as an institutional practice.

Finally, a number of legitimacy interests were served by a well-functioning complaint process. These included the legitimacy of the IRBs' substantive decisions about complaints, but also legitimacy of the institution, particularly in its relationships with research communities, as well as the legitimacy of science more generally, as some later quotes will demonstrate. As one informant noted, "We protect human subjects and we facilitate research at the institution, because research with human subjects does improve healthcare at the end of the day. . . . it's important that our institution be trusted to have the best interest of our patients and you know, um, society in the research that we're doing."

In addition to these intuitive process values, some informants also sought to advance the values of the Belmont Report on ethical research with human subjects. These particularly included respect for subjects' autonomy and the need for beneficence and non-maleficence toward research subjects. These values might be reclassified into the interests above, such as dignity and equality—but the Belmont Report is unique to the lopsided power structures in the research setting, and may be less instructive for other types of IDR.

¹⁰⁸ Christine Grady, *Enduring and Emerging Challenges of Informed Consent*, 372 N ENGL. J. MED. 855 (2015); Tom L. Beauchamp, *Informed Consent: Its History, Meaning, and Present Challenges*, 20 CAMBRIDGE Q. HEALTHCARE ETHICS 515 (2011).

¹⁰⁹ Matthew E. Falagas, et al., *Informed Consent: How Much and What Do Patients Understand?*, 198 AM. J. SURGERY 420 (2009).

¹¹⁰ *Id.*

¹¹¹ Amulya Mandava, et al., *The Quality of informed Consent: Mapping the Landscape. A Review of Empirical Data from Developing and Developed Countries*, 38 J. MED. ETHICS 356 (2012).

D. Elements of Process

Despite the lack of regulatory guidance on how institutions should handle research-related disputes—which might be expected to generate some heterogeneity in dispute system design—almost all institutions have developed similar and procedurally flexible dispute resolution systems. Even where some institutions differ slightly (e.g., a few hold institutional insurance for subject injuries; a few request local community leader involvement for disputes arising in foreign or culturally distinct groups; a few have a patient representative), the contours of the basic process remain the same. Although this may result in part from the process of AAHRPP accreditation, AAHRPP does not mandate particular dispute system design features, and even the institutions that were not accredited handle disputes similarly. This Section will therefore group all types of institutions together for the analysis.

Across institutions, complaint resolution processes most commonly resembles binding arbitration for disputes that are not the result of a factual misunderstanding. For minor disputes arising solely from a misunderstanding or miscommunication, the process may be more similar to facilitated negotiation or even simple education. All processes are developed and managed internally by the IRB, and they rely on the IRB to issue binding decisions as a third-party neutral vis a vis the participant and investigator. Processes follow a rough timeline of complaint receipt, internal discussion of procedural options, “fact-finding” carried out directly by the IRB or a research compliance team, deliberation by the IRB, and issuance of a binding, written resolution enforced by the IRB’s authority to approve or disapprove the research protocol. The remainder of this Section will consider the origins of these processes, procedural similarities across institutions, and the chronological series of steps in the process.

1. IRB as Dispute System Designer: Process Origins and Design

Almost all the institutional processes in this study arose informally within the IRB and solidified over time, as IRBs received specific, but rare complaint calls from research subjects. Where institutions had an ex ante process, it was typically created as part of a broader reorganization of the IRB, or it was imported by a new director or chair familiar with a process from a previous institution. A minority of institutions had no written process for managing complaints; they considered this an “office practice,” or believed that they experienced too few complaints per year to require a written procedure (“I mean it happens maybe five times a year so, uh, knock on wood”). The likelihood of having a written policy differed little depending on the type of institution (hospitals, universities with or without medical schools). These written procedures were internal, and although several institutions post them internally, none described making them available to research subjects at the time of enrollment. No institution mentioned consulting subjects or subject representatives systematically at the time of process design.¹¹²

Where institutions had written procedures, most had developed them to fulfill the requirements set by AAHRPP.¹¹³ Many, but not all, had consulted other institutions’

¹¹² One institution did, however, involve a patient representative throughout the process and involved that person in the process design.

¹¹³ Eighteen of the thirty institutions were accredited or pending accreditation, including all six hospitals, 12 of the universities with medical schools, and none of the universities without medical

policies at the time of accreditation. Informants at other institutions, including non-accredited programs, noted that they had developed written policies unprompted to increase efficiency (“[Before our written procedure,] not everybody was consistent, things were getting missed.”), and to increase consistency across protocols and over time (“I think that’s your biggest, you know, benefit is making sure that everything is handled in a fair, unbiased, consistent manner.”).¹¹⁴ The central goals of process standardization were to ensure similar treatment across all participants and investigators, and to reduce biased procedural decisions that may arise from prior knowledge of the investigator.

Whenever an issue came up that we needed to resolve, we realized that we shouldn’t do it ad hoc, you know depending on the PI [principal investigator]. If we knew the PI was a good guy to do one thing versus, um, doing something else. So we, we realized back then you’re much better off to have upfront processes put into place -- to treat everyone the same -- and go down the same algorithm of decisions -- versus a hit or miss, which is you know what we were doing before we had the SOP [statement of procedure] in place.

It’s really important to us as an institution and as an office specifically that we want to set precedent. Like we want to treat each case as very similar, we want to have a very similar outcome and so if we determine that we have a different outcome, we want to look at why. . . . There are investigators that have, uh, have kind of proven themselves to be very quality investigators, and then certainly I think every institution has investigators that are known to be a little bit less by the book. . . . But if the same complaint came in, the equivalent complaint came in under the same two, you know, under these two investigators, they should be handled exactly the same with the same neutral approach.

Both those with written and unwritten procedures, however, believed that a written procedure would be important in the event that a subject complaint resulted in litigation. For example, one institution without a written procedure suggested that they may be “at risk for not having it more codified But, you know, usually something bad has to happen and then you become codified.” An institution with a standard written process noted that a key motivation was the belief that own compliance with internal procedures would have value in litigation.

Some complaints . . . were bypassing [the director’s] office and going right to [the IRB] committee. And they were meritless. And then there were other complaints that would come to me but there was no formal process -- there was no standard operating procedure. . . . And so we just codified the, um, process flow. . . . You know, if it did get to litigation we -- we could say that we were or were not following our own internal policies. So [we shifted] from no policy to policy. Based on experience, we knew what worked and what wasn’t working. We knew where exposures were . . . legal exposures, regulatory exposures.

Most institutions noted that they continued to revise and update their processes over time, to respond to changes in complaints or the institutional environment (“We learn what works and what doesn’t work and what’s more efficient for the participant and the study team. . . . It’s a continual learning basis.”). Whether procedures were written or unwritten, however, basic procedural features and proximate process goals were similar across institutions, and all relied on the IRB as a third-party neutral, as the next sections will note.

schools.

¹¹⁴ One institution had also interpreted the federal regulations and OHRP guidance on mandatory reporting of unanticipated problems to require a written process for resolving complaints, in the event that complaints alleged such problems or noncompliance. Other institutions, however, had not interpreted the regulations this way.

2. IRB as Complaint Line: Initial Contact

All IRBs provide their contact information to subjects via the informed consent form, or if a verbal informed consent process is used, subjects receive independent notice of the IRB contact information. Most subjects communicate complaints by phone, although some IRBs noted receiving isolated complaints by email or (sometimes-anonymous) written letter or email, and these IRBs responded by phone if possible. Phone calls may direct to a general office, but they are then redirected to a single person such as the director, administrator, chair, or manager of the IRB.¹¹⁵ Institutions that received complaints through other channels, such as those going to the president or provost's office in a university, typically referred these back to the IRB. Most institutions do not require a written complaint; instead, the IRB personnel prepares a written description on behalf of the subject at the time of the call, and some fill out standard forms during the call to ensure that they are obtaining all the relevant information.

Almost without exception, the informants emphasized the importance of the initial conversation with an aggrieved subject. The immediate goals of this conversation are to obtain a detailed description of the complaint, to identify the relevant protocol and investigator, to identify any previous efforts to resolve the complaint with the investigator, to identify threats of violence or psychological needs, and to understand the remedy that the subject was requesting, if any. But at the time of first contact, IRBs also seek to provide the subject with a full opportunity to voice their complaint without interruption, to ensure that the subject feels heard and respected, to express respect and empathy, and to convey that the subject has been heard by someone who has the institutional authority to resolve the dispute.

The number one thing we're trying to do is to listen, even if we don't get a complete understanding of the complaint, I mean, that's another goal, but the most important thing is that the person on the other end hangs up the phone feeling that they were heard. They want to get to somebody right away, without having to go through lots of different people, who has the authority and responsibility to listen to them and to, who can help them. So that's number one. And then number two, our perception is that, uh, they want somebody who's going to listen, um, in an empathetic way.

The primary goal actually is to ensure that the subject feels heard. To make sure that whoever is calling, whatever the concern is, that they have some hope that in fact, uh, someone is going to take their call seriously. And while we obviously cannot, uh, promise to the caller that whatever resolution happens will be done, you know, to his or her satisfaction -- we can at least reassure the caller that, um, they've, they've reached someone who is going to help them.

I want to, um, allow them to tell their story . . . being, you know, caring and, um, respectful. . . . I would confirm back to them that, you know, we understand that it's upsetting to them Once I've heard from them I like to clarify back to them what I heard and what my understanding is of their concern . . . [I'm] making it clear that their concerns have been heard and understood. People really need to be heard.

Informants noted that hearing the subject could serve instrumental reasons—it can help defuse emotions and ensure that the process is responsive, and sometimes having a

¹¹⁵ Several forms also provide numbers for multiple contacts at the IRB, in cases where the IRB chairs also conduct research and may have complaints arising in their own research studies.

voice fulfills the subject's entire goal in complaining ("Some people will call and say, you know, here's my grief, but at the end of the day they just want to vent and don't really want me to follow up with that, and don't want to leave their name and number."). Informants also noted, however, that this also serves inherent values that might be described as dignity interests, at least in our taxonomy of process values—here, these interests include the desire to be "taken seriously" and to have someone in power acknowledge the emotional impact of the perceived wrong. These expressions of empathy can also promote legitimacy of the process and institution, as one informant noted:

Usually if they know that you're concerned about them . . . this reflects on us as much as anybody else. We want research to be done ethically. We want all research participants to feel like they can come to us with any um concern or complaint and so I usually reassure them to let them know that we take every complaint seriously, that we'll investigate it, and we'll work with them until the problem is resolved.

3. IRB as Communicator: Ongoing Communications with Participants and Investigators

At the time of initial contact, most institutions also offer participants some input on process and offer procedural safeguards. All institutions offer subjects the opportunity to make their complaint anonymously, without disclosing their identity at all, or confidentially, without disclosing their identity to the investigator.¹¹⁶ (They note, however, that anonymity or confidentiality may limit the options for resolutions in complaints regarding compensation, investigator misconduct, or harassment.) IRBs typically give participants the option to continue the process toward resolution or corrective action, or to stop the process after the initial call. One IRB member noted that giving the participant this flexibility was an important part of respect for autonomy, which is a core principle of the Belmont Report ethical guidance for research. In the dispute resolution context, this aligns with the broader dignitary and participatory values of process.

If they, if they want it to just be a venting session, I'm here to listen. But if they, if they do need some additional follow-up I wanna make sure that they have the control as much as is appropriate. . . . Research again is not . . . your standard clinical treatment. . . . Our participants are volunteering to be in this research, that they're not compelled, and I think it's important that we respect and honor their contributions to the research. They can withdraw at any time and I, I guess it's just part of the respect of persons, kind of getting back to that ethical principle, um, in the Belmont Re[port that I think is, is important.

Another recurring theme throughout these interviews was the need to maintain continuous contact with participants and investigators, including informing them of the steps of the process as they occur. Informants viewed this communication channel as in part an extension of voice and the value of participation, as well as serving broader dignity goals; as one informant noted, "It's important to be transparent . . . it usually turns out to be much worse if you don't keep the, the complainant in the loop so that they feel like they're actually being listened to . . . I think transparency and neutrality are more important because I'm not really sure there is such a thing as the right resolution." Some IRBs set frequencies for re-contacting subjects and investigators during a complaint, such as making contact on a weekly basis.

¹¹⁶ One institution even maintains a fully anonymous, non-staffed phone line that anonymizes calls, for people who wish to leave a message without any link to their identity.

Informants also noted the need for transparency of process to improve satisfaction among both investigators and subjects. One informant, for example, described a change in practice to discontinue an informal process that was “never really clear on the policy” and “would cherry-pick what they wanted to do.” In their new process, “if somebody had a complaint we would send an email and explain what our steps are going to be [to the subject] and a researcher if we were going to audit them . . . we tr[y] to be user-friendly and have clear understanding of what the role is and what’s going to happen . . . and it’s made the situation better.” Another agreed that transparency directly affects perceived legitimacy: “Communication in really key . . . in order to be transparent. . . . I think even in the tough situations most people are respectful of how you undertake the process, knowing that it is a difficult process.”

IRBs are aware that the stakes of complaints are high for investigators, particularly when subjects express concern about the investigators’ own conduct or noncompliance. As one informant noted, researchers are “typically in a defensive stance” during complaints. Transparency of process was viewed as an important safeguard for investigators, who may also have more notice of IRB practices through investigator training, repeated interactions with the system, or access to internal institutional policy documents. Information about process can also alleviate investigators’ feelings of being wrongly accused or the target of bias, as one informant noted: “We have to let them know that we have to investigate every single call regardless of feelings, regardless of anything . . . and a lot of times they know it’s a process that we have to go through.”

4. IRB as Mediator: Process Selection and Resolution of Minor Complaints

After the initial contact, the IRB director or manager makes a preliminary determination about the severity and likely veracity of the complaint.¹¹⁷ Where there are urgent or emergency issues involving risks to subjects, the most senior IRB official (the chair) or a subcommittee of the IRB will immediately assemble and recommend emergency measures, such as suspending study activities. But for most types of minor complaints, the IRB personnel will begin by contacting the principal investigator of the research study by phone or email, to identify whether the complaint can be easily resolved. Many complaints are easily classified as minor issues that can be resolved via communication between the subject and principal investigator (e.g., missing compensation), or via a direct, second conversation with the individual (e.g., explaining why the person was not eligible for a particular protocol). The IRB director, manager, or chair typically takes these actions directly,¹¹⁸ notifying the principal investigator or re-contacting the complainant to explain features of the study or informed consent form. A number of IRB chairs noted a practice of directly facilitating conversations between subjects and investigators, with the chair personally serving as a third-party mediator to ensure that the communication went smoothly.

¹¹⁷ Several informants noted that concerns about veracity can be particularly important for complaints arising in psychiatric studies. “A lot of the complaints may also be from psychiatric patients . . . So I sort of probe how closely their complaint is grounded in reality.”

¹¹⁸ Where subjects report not having spoken with the investigator yet, many IRBs will suggest that the subject do so directly before proceeding.

[I] try to set up a, you know, a meeting between them and the investigator so they can address these issues. . . . Most conflicts I think it's best when everybody is sitting down and talking to each other. . . . That's one of our first outreaches with any sort of problem, whether it's just an investigator or a study problem, is to try to get everybody in the same room and talk about it. If it looks like it's a problem that could be solved by just people talking to each other or looking at what the different options are, that's always, that's always our first approach.

The time to resolution for these minor complaints is typically hours or days, and multiple informants described the procedure in these cases as a “customer service” approach, centered on listening and the subject’s desire to be heard.

5. IRB as Fact-Finder: Iterative Investigation and Consultation for Serious Complaints

Where complaints do not arise from miscommunication or misunderstanding, however, the process escalates to resemble arbitration, in which the IRB takes on both a fact-finding and adjudicatory role and imposes a resolution that is enforced by institutional authority over the research protocol. The IRB chair, along with any other IRB personnel who initially received the complaint, makes a preliminary classification of the issues, rights, and individuals at stake, and determines whether other institutional actors should be involved in the resolution process. Where the IRB reports to an additional institutional authority, such as the vice president or chancellor for research, the IRB personnel will likely include this person in the decision about involving other departments.

Depending on the nature of the complaint, the IRB may choose to involve a wide array of offices or personnel within the institution. The role of these personnel is typically to provide guidance or to assist in fact-finding. These may include the institution’s general counsel (for complaints that include legal claims, injuries, or potential legal violations, such as failures of informed consent or HIPAA violations), any insurance program for research-related injury, the human resources office for complaints involving whistleblowers or investigator misconduct, the risk management office, the regulatory affairs department, FERPA officials, the office for privacy and HIPAA, media affairs (for disputes receiving media attention), institutional officials serving as research subject advocates or patient advocates, university ombudsmen, campus police or security for disputes where subjects or investigators may threaten violence, institutional officials for sponsored projects, and departmental heads or chairs of the investigator’s department. All dispute resolution processes for complaints alleging noncompliance with protocols will also involve a compliance team, which may be a subcommittee of the IRB, a single IRB officer such as a quality improvement officer, or a separate arm of the broader human research protection program.

The IRB chair and other institutional officials may also gauge whether the complaint requires contacts with people outside the university—for example, research sponsors who may need to approve protocol changes, local police who were arresting participants leaving a study for sex workers, a state agency that had made a name-based registry of cancer patients available to researchers, a local school board for a dispute about informed consent for school-based research, or a tribal council for a dispute over the return of biological samples to tribe members. IRBs also work with foreign IRBs, for international research protocols that require review by institutions in multiple countries.

After identifying the relevant stakeholders, rights, and interests, the IRB typically begins a flexible and sometimes iterative process of fact-finding, consideration of facts and interests, and communication with the investigator, research staff, participant, and other institutional or outside actors. The fact-finding process may include a formal audit of study materials or less formal interviews with the investigator and study staff. The IRB may conduct this process itself through a subcommittee or individual staff members;¹¹⁹ it may also use a compliance office or risk management team.¹²⁰ The process can last up to six months or even a year for complicated or contentious disputes, but more typically lasts about one month.

6. IRB as Client: Outsourcing Disputes

During consultation with other institutional stakeholders, senior members of the institution may decide to reallocate control of the dispute resolution process to legal counsel or human resources departments. Where this occurs, the IRB loses jurisdiction over the dispute. “[If] the institution wants to move forward with it or take it to a different level or address that we kind of bow out from a jurisdiction perspective.”

Even when the IRB retains management of the dispute, however, they may rely on institutions’ legal counsel for guidance, interpretation of applicable institutional policies or external regulations, or communication with research participants’ counsel. Some informants believed that legal counsel were reliable supporters and valuable resources for most complaints. But others noted that legal counsel could actually complicate complaint resolution; their concern for institutional liability encourages defensive communication with subjects, rather than the empathy and concern that most IRBs thought was the necessary tone to achieve a resolution.

We don’t necessarily have to bring the attorneys in right from the beginning, and they don’t drive the process. . . . They’re focused, of course, on protecting the university . . . and that’s great. But that often is at odds with trying to resolve the participant complaint. In an ideal world, everybody would agree that resolving the complaint is not only the right thing to do but will prevent the litigation. But sometimes those are a little bit at odds and so we get into sort of a—if the attorneys are prominently involved—sort of a protective mode where um, we’re not necessarily free to be as compassionate. Even if we’re not agreeing with the participant necessarily, we want to be able to still interact with them in a way that displays empathy and compassion, and sometimes that can be a little bit of a challenge when the attorneys are involved.

A few research institutions had instituted a procedural innovation to address protocols that take place in international or culturally distinctive settings, where subjects may be uncomfortable with approaching the institution directly. These institutions sometimes required investigators to appoint a local community leader to assist in resolving disputes arising in any protocols; this person could liaise between the subject community and the institution where needed. The community representative was listed on informed consent

¹¹⁹ One hospital also reported having institutional legal counsel attend fact-finding interviews, “to give [research staff] comfort and reassurance” that they will not be penalized for honest responses.

¹²⁰ In one dispute concerning the behavior of the IRB itself, the IRB asked another institution’s IRB to assist in the factfinding and dispute resolution process.

forms and became a point of contact for receiving complaints, and also an active part of the resolution process for any complaints that rose to the level of the IRB.

We look for an alternate, uh, position in the community, a trustworthy person in the community to accept those and refer them to us for handling. . . . It's all a part of being sensitive to the population that are being recruited. . . . It includes having a person in that community who would be perceived as being impartial and would listen and refer the, the problems and concerns to us It can be used in remote, anything that is remote from our site or which is culturally inaccessible, like an Indian tribe. . . . [And] for our sake they would be um, um at a leadership community leadership level that they would in an informed way communicate with the IRB here.

This institution raises interesting questions about the relationship between the research institution and the participant population.

7. IRB as Adjudicator: Deliberation, Decisions, and Appeals

When fact-finding is complete, IRBs proceed to deliberation, which remains internal to the IRB for most types of complaints. Factual findings and the results of conversations with various stakeholders are recorded and assembled by the IRB, along with guidance from other relevant institutional actors. The IRB may designate a subcommittee or ask the full board to examine the factual findings, guidance, and interests at stake. This decision body recommends a preliminary solution that may be acceptable to the parties, including any proposed remedies or corrective action plans. Many IRBs at this stage will communicate directly with the principal investigator in advance of the final decision, attempting to find a voluntary set of protocol corrections or a remediation plan that the investigator would find feasible and acceptable. Several informants described this process as prioritizing transparency and participation throughout the crafting of a resolution, while others noted that unrealistic corrective action plans may undermine the durability of the resolution:

We do try to be transparent, um, listen to both parties, and then come to collaborative solutions that would really involve all parties trying to create the solution My preference is not to impose solutions as much as to say, "What would be your solution given your particular environment that you conduct the study in?" Of course, if it's a regulatory piece then we have no flexibility, then we tend to impose, but even within that imposition it would be my style to say, "Well, how is that going to work for you?"

We work together on a solution that's more of a learning experience. We don't want it to be punitive for either party . . . especially our PIs because sometimes . . . they didn't realize they were doing anything wrong. . . . So depending on the solution, a lot of times we may involve the PI into the solution.

We don't want to impose . . . a bunch of strict regulations on a study team that will in essence make them be noncompliant in the future if they're unable to fulfill that corrective or preventive action plan.

The process concludes with a full IRB decision to approve a corrective action plan and to formally issue a written letter to the principal investigator, setting forth the facts and corrective action requirements. IRBs often notify the subject of the final resolution as well, although the subject does not typically receive a copy of the same letter. The IRB determines what will be disclosed to the participant at this time, which may be in writing or by phone, and may contain less detailed information. As one informant noted, "We may

say [an investigator was] disciplined but we won't say . . . what the specific disciplinary action was because . . . we have to keep in mind the faculty member and the investigator, their rights.”

According to many informants, the IRB's authority to make binding decisions on research-related complaints arises from the federal regulations, which task IRBs with the approval or disapproval of research protocols. As one informant noted, “Because our IRB, you know . . . [we] have that federal regulatory mandate to be the final decision makers . . . even when people appeal [an adverse decision], it typically doesn't result in a significant change.”

After the final decision, almost all institutions give the principal investigator a right to appeal for reconsideration by the chair, the full IRB, a vice president for research, or the chief medical officer. No institution described making this option available to the subject, because subjects cannot experience sanctions as a result of a complaint. But when prompted, many IRBs said that a subject who is dissatisfied with the resolution of their complaint could likely obtain reconsideration as well.

Subjects who invoke the dispute resolution process do not give up other legal remedies; nothing forecloses a public lawsuit after the process ends.¹²¹ Informed consent forms do not require subjects to use the dispute resolution process at the institution—mandatory arbitration is curiously absent in this context. But because so many disputes are based on non-justiciable interests rather than legal rights, the IRB's decision is typically the only available remedy. Investigators can (and sometimes do) sue institutions in connection with research-related disputes, but individual subjects typically are not involved in public investigator-institution disputes.

8. IRB as Enforcer: Remedies

IRBs noted many options for remedying research-related injuries, all enforceable by the sanction of closing research protocols that do not comply with remediation plans. Financial settlements were possible but rare, and the negotiation of these settlements typically involved legal counsel. Only a small handful of institutions had a public policy of compensating research-related injuries, either by insurance or institutional funds; a majority, however, noted that they either paid for treating injuries at their own facilities, or they eventually provided funds for treating any research-related injuries that are not covered by subjects' own health insurance. This is an important informal policy, given that most consent forms specifically state that research sponsors and the institution are not obligated to pay for treating research-related injuries. Informants did not describe apologies as an available remedy, but noted that subjects did receive explanations of events where relevant.

Other remedies include changes to individual protocols, such as mandatory changes to training and supervision procedures for research staff, changes in recruitment strategies, changes to the informed consent process, or changes in criteria for initial or continued eligibility. Some of these protocol changes are reportable to study sponsors, as are

¹²¹ It is possible, however, that subjects who receive compensation for injury do need to waive the ability to sue as a condition of settlement. *See* Pike article. But these are a minority of cases.

complaints that are determined to arise from serious adverse events or unanticipated problems involving risks to subjects. IRBs can also require training or directed education of investigators or staff on issues like informed consent or record-keeping. For more severe or irremediable violations, IRBs can terminate studies or entire lines of research, mandate the destruction or nonuse of data, or require the return of biological samples to subjects. Where investigations reveal serious or recurring noncompliance, scientific misconduct, or HR violations, researchers may also experience professional sanctions or discipline through the HR department.

Some complaints led to thoroughgoing changes in institutional policies, such as the discontinuation of recruitment practices that involve cold-calling, changed policies for the supervision of students, a discontinuation of studies that consented participants under the influence of alcohol, new policies for training researchers and staff, and changes to institution-wide informed consent practices.

9. IRB as Record-Keeper: Missed Opportunities

Most institutions kept written records of complaints, but these were typically filed under individual protocols; only a few institutions systematically recorded complaints using a method that would allow for analysis over time or across protocols. Feedback from dispute resolution programs could assist IRBs in identifying research risks and burdens, but IRBs are neglecting this opportunity to use disputes as information. Ideally, IRBs should record complaints in a manner that would allow personnel to aggregate or compare issues across protocols. A periodic analysis of these complaint data could help IRBs anticipate risks and burdens at the protocol approval stage, rather than waiting for complaints to arise. IRBs could also use these data to identify recurring complaints arising from particular departments or protocol types, which could be remedied by improvements in investigator training or institutional research procedures.

E. The Centrality and Limitations of Procedural Flexibility in IDR

Throughout the interviews, the IRB informants consistently noted the advantages of a highly flexible complaint resolution process.¹²² Even where procedures were written, informants described leaving broad latitude to select among process options, or supplementing the written process to include additional elements.

We have to have a written policy that we handle complaints, but we leave it as open as we possibly can, um, we provide a range of possible responses depending on what the, you know, the level of severity, etc. . . . You don't want to lock yourself into having to, you know, you don't want to say in your policy we will respond in writing to all complaints if that's not appropriate. . . . So you then leave yourself open to being able to, um, respond in a, you know, um, issue specific manner that's appropriate for what's going on.

[The process is] just based on the situation at hand. . . . We have on paper a policy and process. . . . But if we, you know, run into an obstacle or a snag or, you know, if we needed additional information, we might make a decision that's not written somewhere. But again,

¹²² The informality of IRBs' own protocols, records, and procedures may amuse many researchers who prepare highly detailed and inflexible protocols to comply with IRB requirements. Flexibility, however, serves several key values in the IDR process, as this Section suggests.

only with the same intent, which is . . . [that] all parties are being, you know, properly addressed, you know, properly, um, given the proper opportunity to kind of speak.

Informants believed that the principal benefits of procedural flexibility were the opportunity to tailor the process for complaints with a range of rights and interests; to involve all relevant institutional and outside personnel in the response; and to provide full voice to any unforeseeable parties that may have a stake in the events or their resolution. Some of these benefits serve efficiency—that is, standardized procedural features may waste time and resources. For example, it is costly in time and manpower to conduct full audits for complaints that might be easily resolved through facilitated negotiation. These efficiency benefits may indirectly serve the value of participation, by freeing up time and attention for more resource-intensive complaints. As informants described it, however, procedural flexibility also directly serves participation and legitimacy by promoting voice and inclusion of all parties. Informants believed it would be costly to legitimacy, destructive to community relations, or corrosive to the durability of a resolution if processes exclude stakeholders beyond the subject and investigators—as in the examples involving tribal leadership, community-based organization, school boards, or local trusted officials in overseas protocols. The procedural flexibility embedded in these ADR systems allow for the involvement of all relevant stakeholders on a case-by-case basis, which informants commonly described as a procedural goal. As one informant noted:

Each situation almost is unique And the biggest principle that we try to follow that's sort of a general principle . . . is to spend a lot of time being absolutely certain that we have consulted with all the appropriate parties And that means at information gathering, identification of an appropriate, uh, resolution and action plan, and then conducting and carrying out that action plan, and then closing the loop when the whole thing is done. So that's kind of the general principle that we do that is common to all the complaints . . . because we've had some real problems when that didn't happen.

Many informants stressed that a standardized process would be inadequate to handle complaints, and some believed that the interpersonal skills of the dispute *processors* are likely more important for a thorough resolution, compared to the process elements itself.

These complaints are as variable as there are people. . . . I'm wondering if you could or whoever develops this could come up with enough of a cookbook or a recipe, um, that it's going to be applicable to the next five cases that came in the door Some of it depends on who you have handling [complaints], just how adept they are at dealing with people, um, more than processes. . . . I don't know that this is going to be an area that just immediately lends itself to here's, here's, here's the one template or recipe you can all follow and apply this to every complaint you get

But despite the virtues of procedural flexibility, informants also noted that a flexible process introduced complexity, unpredictability, bias, and difficulty in passing on institutional knowledge. Informants noted that flexibility may lead to a lack of transparency and inconsistency.

I think a strength is our flexibility or the nuances. I mean, I enjoy the autonomy to handle these things in the, uh, in a professional expeditious manner, as I see fit given the nature of them. But I also see, particularly as like a noncompliance gets tied in with this, the fact that we don't have, if you will, very transparent, codified, step by step procedures that we follow every single time can bite us.

The flexibility is the upside and it's the downside It means that I am making decisions. . . . And that's my job. . . . But I have to decide, you know, pretty quickly what the correct response is and who to contact and where to go with it. . . . So having that, um, in the hands of a, a single individual . . . almost always it's, it's a single individual who's handling it and that, I think, might be, that could be a problem.

Informants also noted that the embedded discretion for IRBs to select among processes can also make it difficult to train successors in the process more generally, which could lead to inconsistency over time.

One doesn't really know if there's a right or wrong way of dealing with this. You just do whatever makes sense for the participant. . . . [There's] a lot of flexibility. And a lot of discretion. Uh, it's up to the discretion of, um, me for the most part. That's -- that's the problem. . . . [It's] not impossible [to train someone else]. The challenge is that, um, it's a subjective process that depends on my view of what's going on initially it would be difficult to document, if necessary the triage process, because that is based on, largely on subjectivity and intuition and a lot of intangible characteristics.

Informants therefore viewed the deliberate exercise of procedural flexibility as a means of serving participation and legitimacy values, as well as the more proximate goal of system efficiency. But flexibility was not an unabated good, and it complicated values such as procedural predictability and equality, as well as the proximate goals of consistency and system transparency. The following section will consider informants' appraisals of process goals and values more generally.

IV. APPRAISING IRB-MANAGED IDR SYSTEMS

Apart from asking informants to describe their procedures, the interviews also asked informants to appraise the strengths and weaknesses of their complaint resolution systems. Informants identified a number of strengths, including the contributions of procedural flexibility. But informants also noted problems from their perspectives, including concerns about low uptake, the capacity of the IRB to act as a third-party neutral, frustration with available resources, and the potential for inconsistency across participants or time.

This Article now moves from a descriptive to normative view to provide a critical appraisal of IRBs' IDR systems. Strengths include the ability of these processes to consider both rights and interests, as well as the voluntary nature of participation and the continued access to litigation where participants choose to file claims. But among system weaknesses, I echo some of the informants' concerns, focusing more specifically on participant non-consultation, low uptake, and IRBs' institutional capacities to behave neutrally and skillfully in the dispute resolution role. This Part will first describe informants' appraisals, followed by my own.

A. Informants' Appraisals

Beyond the strengths afforded by procedural flexibility, informants described many other advantages of their complaint resolution processes. The institutions that compensated subjects who sustained research-related injuries—either by institutional insurance or by de facto provision of medical treatment—viewed the availability of a financial remedy as a particular strength. (In contrast, institutions with “fuzzy” language on injuries or policies of nonpayment were a source of great frustration to informants, who

would prefer to have the option to make subjects whole for physical injuries.) Many informants noted that their process functions well to give both subjects and investigators the opportunity to be heard and respected, and those with a written or standardized process were more likely to describe consistency and transparency as system strengths. The personal qualities of individuals involved in the process—such as substantive knowledge of the regulations, experience handling complaints and investigators, personal experience in the investigator role, interpersonal or counseling skills, and (sometimes) dispute resolution training—were also viewed as strengths. Informants appraised decision quality in terms of accuracy about facts, finality and non-recurrence of the dispute, parties' satisfaction, and the ability to enact system-level change for disputes that indicate a systemic problem. Most institutions believed their processes functioned well on these measures, and believed that they had struck the best possible balance between protecting participants, treating investigators fairly, and safeguarding the interests of the institution.

1. Access and Uptake

Despite the perceived strengths of their processes, informants believed the frequency of complaints was surprising low, and many were puzzled by the shortage. As one informant said, *“I’ve always felt that the number of complaints we get is remarkably small for the size of our research operation The information [about our IRB] is really prominent in our consent forms, but . . . it just seems odd to me, um, that we don’t have more.”* Informants who sought to explain this shortage of complaints offered different explanations for the scarcity. Some noted that research staff are likely the first port of call for a subject complaint, and these informants emphasized the need for IRBs to train investigators and staff to respond thoroughly to subject concerns. Several institutions that primarily conducted social and behavioral research suggested that complaints are infrequent because their research portfolio tended to be minimal risk, or excluded clinical trials. One research hospital informant noted that complaints are likely low because all hospital patients know they are receiving research-related services, giving them a different set of expectations about their care. Others suggested that participants enrolled in therapeutic research are less likely to complain, compared to healthy individuals who participate in research for financial reasons and may have more complaints related to compensation.

But as interviews continued, many informants suggested that research participants may be unable or unwilling to call the IRBs with complaints. Participants may not understand research protocols, making it difficult for them to form expectations – and thus, difficult to identify when they have experienced a wrong. Even if participants are aware that the IRB provides a venue for dispute resolution, they may be fearful of the consequences of complaining. Subjects enrolled in ongoing protocols or clinical care may also fear retaliation or stigma after lodging a complaint.

It’s probably the tip of the iceberg underneath that one [complaint] in two years is people that were frustrated and wanted to complain but they talked themselves out of it . . . I think there’s some stigma attached to, um, calling up somebody that works for the university . . . I think the person would be uncomfortable to call the university.

We have a low number, and I’d like to think that’s because everyone’s so excellent at what they do [But] I fear that sometimes there’s people that might want to share something or talk through something, and they don’t share because . . . [they] are also patients . . . and

the research study might even be headed by the person who also provides their clinical care We definitely try to set up a system of being anonymous and we keep them separated from the investigator and all that good stuff, but even with all those protections I feel people might hesitate to say, or they might not even be sure what to complain about. You know what I mean, they're not always 100% positive of how a consent process should really be executed. Did they have enough time to think through it and ask their questions? They might not even feel confident, if they've had a bad experience, that they had a bad experience. I'm always very surprised that we have the small number that we do.

Sometimes the researcher is also their physician that they have known for years and maybe the complaint is about some aspect of the study, but they don't want to sour the relationship that they've had with a certain specialist or something like that.

Finally, informants also noted that subjects may be uncertain about the process for dispute resolution, and this uncertainty may make the process inaccessible. Although the consent forms consistently directed participants to the IRBs, informants expressed concern that this information was not prominent or clear enough to empower subjects to use the system.

I'm sort of surprised that more people don't call us or ask questions . . . I just think people don't necessarily think to call us, you know? I've often thought maybe we should, it would be interesting to do a study about putting the IRB's phone number first on the consent form to see if we got more calls. Because I think with that many protocols . . . I think we'd have more calls.

I think that people probably don't report it enough, and I don't know if that has to do with, maybe perception of research compliance, or if our participants really are just not aware that they can report. . . . I definitely think that there has been . . . some instances where a student or participant could complaint, but they just don't . . . because they just brush it off, or because they, you know, are really not aware of the procedure, or if they just don't understand the importance of reporting.

Some may argue that low uptake of a complaint resolution is appropriate for research-related complaints; in a setting where many complaints may entail non-justiciable or minor harms, lumping the complaint or exiting the relationship¹²³ may be more efficient for many subjects and institutions. Institutions certainly benefit from the comparatively low administrative costs of a seldom-used complaint procedure. But the low frequency of complaints may be problematic in this context for several instrumental reasons, even without considering inherent value of dispute resolution for subjects. First, silence on minor complaints obscure systemic problems that eventually expose institutions to significant legal risks, such as deficiencies in informed consent procedures. Second, dissatisfied subjects who feel they must lump their disputes can contribute to difficult relationships between institutions and their surrounding communities, which can spill over into other conflicts. Third, when subjects choose to exit scientific research or decline to reenroll in future protocols, the institution must divert more resources to study recruitment and retention, thus increasing the costs of research and reducing the feasibility of human subjects protocols. The disproportionately low frequency of complaints, therefore, may not be fully in institutions' best interests at present.

¹²³ Jost, *supra* note 29, at 314; William L.F. Felstiner, *Influences of Social Organization on Dispute Processing*, 9 L. & SOC'Y REV. 63, 81 (1974)

Fully explaining the low uptake of institutions' dispute resolution processes requires more research with participants themselves, in order to explore perceptions of research experiences that give rise to complaints, their awareness of the availability and content of a complaint resolution process, and their expectations and perceptions of these institutionally controlled ADR systems. But my research with the designers and implementers of IRBs' processes suggests that research subjects do not receive sufficient information to make the complaint resolution process accessible—perhaps because they do not understand or believe that they have grounds to complain, because they are unaware of the forum, or because they are unaware of the procedural safeguards the forum provides. And moreover, even if participants are aware of mistreatment and the venue for complaint resolution, they may nonetheless be deterred by fears that complaining will result in stigma, retaliation, deterioration of relationships with care providers, or loss of access to services. The low uptake of these processes suggests that many subjects do not currently view them as meaningful options for complaint resolution.

2. Neutrality

Despite agreeing that IRBs had authority to resolve disputes, some informants expressed discomfort with placing the IRB in the role of a neutral third party. The most visible stakeholders in complaints are the subject and the investigator, but complaints also implicate the institution, the broader communities of which subjects are a part, and the legitimacy and progress of science as a greater social good. The federal regulations task IRBs with protecting subject welfare, and some informants suggested that this biased their judgments to favor subjects. As one noted, *“Because of the way the staff then would view their roles here . . . they're more participant, uh, oriented. And I always just have to point out to them . . . you need to give the investigator an equal chance.”* Another concurred: *“I do think we need to remain neutral though in before until we get all of the facts. . . . But our end and ultimate goal is to protect the rights um of the participant to make sure they are treated correctly.”* Some informants even suggested that placing participants first was the best way to serve institutional interests: *“I have to follow the regulations to protect the institution, as well as to protect the participant . . . in that way they're kind of woven together. . . . follow the regulations, be accurate, and honor the subject's complaint.”*

But some informants also noted that ties to investigators and institutions can complicate these loyalties. As one reflected, *“You're here as an IRB staff. You need to work for the subject. You you're protecting the subject, not the PI. . . . But the PI is a colleague. . . . So you need to have balance between both discussions.”* As institutional dispute resolution scholars would note, IRBs are institutional arms, staffed by institutional employees, and IRB professionals are aware of their role in protecting their institution throughout the complaint resolution process. As one informant noted, *“I think [neutrality] is important, but I think it's very difficult to achieve . . . for us to be impartial. . . . I do think we're biased toward the institution because of our employment status.”* Or as another noted, *“The first, you know, line of protection needs to be the participants but . . . as university officials there's a, a responsibility to the university as well.”* The burden of neutrality and pressure from the institution can make these dispute resolution processes highly stressful for IRB personnel, as one informant described:

When our office has to engage in a very kind of intense uh investigation and follow up for a complaint . . . it's pretty stressful on our resources and on our personnel. There have

definitely been times when we have uh feared for our safety because an investigator feels their um their career is on the line, and when the institution feels that you know their reputation is on the line. And [when] we're trying to pursue um you know an investigation that may have some implications for the institution . . . we might feel our job is in jeopardy. . . . It's personally very stressful We've been . . . trying to understand the reasons for burnout and turnover . . . in our office. And any compliance office I think, um, has similar issues because it's just the nature of this kind of work, compliance work . . . our turnover is pretty high Our biggest weakness is dealing with institutional oversight, and kind of being able to make our determinations in an autonomous way.

These concerns did not arise in all institutions; some informants reported little difficulty viewing their role as a third-party neutral. As one informant said, "I'm not representing or defending the role of the investigator or any institution, that I'm neutral because our goal . . . our goal is human subject protection and that [resolving disputes is] part, it's part of it so [I'm] definitely neutral." But it is important to note that neutrality may not be perfectly secured through an internal process, and IRBs are aware of these tensions.

3. Resources and Training

In part due to the rarity of participant complaints, many informants noted that they had not received extensive training or professional development to handle disputes directly. A small minority of informants had completed complaint resolution or mediation training, but they had done so for other purposes, such as institution-wide HR initiatives or training for previous employment. Although many informants noted that they felt comfortable handling most subject complaints due to their institutional mandate to protect participants, they also reported uncertainty about how to manage complaints that may involve mental illness, threats of violence, and volatile interpersonal dynamics. When asked what resources could improve their processes, informants were most likely to mention the need for dispute resolution skills building, mediation training, or counseling training throughout the IRB office.

Informants sometimes noted struggling with the manpower and time needed to handle complex complaints, particularly given other IRB functions such as initial and ongoing protocol review. Multiple institutions also reported difficulties documenting complaints in a helpful way, and as noted, most did not document complaints in a manner that would allow for systematic analysis over time. Again, many described this as the result of rare complaints, since there may not be enough for a helpful analysis of systemic problems. As one informant noted, "I would be interested in a little more formal feedback loop . . . if we had data that would show if . . . there's a lot of complaints in a certain area then we could increase, redirect our education program It would be, you know, allocation of resources to prevent [problems]."

Informants also reported having little or no information about other institutions' processes, making it difficult to appraise and improve their systems. This arises in part from the nonpublic nature of these ADR systems, but also from a general lack of professional attention because complaints are currently rare. Many suggested that PRIM&R, the organization for IRB professionals, could build capacity by focusing on this issue in annual conferences or continuing education, such as providing case studies or an

aggregation of best practices across institutions.

4. Consistency and Monitoring

As the previous section noted, some informants expressed concerns about consistency and predictability. In large part, this reflected the procedural flexibility that they viewed as essential to achieving participation and legitimacy goals. But many also suggested that the rareness of complaints may undermine consistency, since the procedures are not invoked often enough to become routine: “I know that we can all improve our processes. It’s one of those areas that we don’t see a lot of them . . . since it’s infrequent and it’s, each case is individual, it’s hard to come up with, you know, systematic processes.”

Some also noted that it was difficult to gauge whether their processes were in fact consistent or successful, because they did not have enough complaints to assess how the system functioned as a whole. “[The process] hasn’t really been tested . . . with all our policies, even in writing, they were in draft form for quite a while. You really don’t know, have you covered everything, until . . . the scenario arises and you pull the policy and you’re ready to walk those steps out . . . You never know the holes until you find them.” Institutions with larger research portfolios with a larger absolute number of complaints are less likely to have this problem, but informants from such institutions still noted difficulties with documenting complaints in a way that allows them to monitor for consistency and systemic problems.

B. A Critical Appraisal of IDR Processes

Taken as a whole, this study has revealed a set of institutional dispute resolution systems with broad procedural flexibility, institutional discretion, and management by institutional employees who perceive an ethical and regulatory imperative to protect subjects—but who also note conflicting loyalties to investigators and the institution as a whole. The system design typically matches the priority that informants placed on values of participation, revelation, and privacy; subjects and investigators have a full opportunity to communicate facts, these parties have some opportunities to shape the process and remedy, the system accommodates both justiciable and non-justiciable claims, decisions are reasoned and almost always written, decisions are enforceable within the scope of IRBs’ regulatory authority, and the systems aim for party satisfaction as a primary proximate goal. To the extent that participation directly shapes party acceptance of the system, the processes serve legitimacy values as well, both for parties and the broader project of scientific advancement.

In relation to a recent framework of preferred design elements for ADR systems,¹²⁴ these systems also have several key strengths: they offer multiple process options (e.g., facilitated negotiation, quasi-arbitration), and accommodate both interests and legal rights. They provide flexibility for complaining subjects to have input on the process, although the processes made little distinction between rights and interests. Participation is voluntary and confidential for subjects (although less voluntary for investigators, who are subject to IRB authority), and the system aimed for transparency of process while parties were

¹²⁴ Smith & Martinez, *supra* note 27, at 128.

engaged in the dispute. Parties may also pursue litigation even after the conclusion of these IDR processes, in most cases.

Despite these advantages, this case study also reveals several key deficiencies of the systems. This Section will consider three problems in particular: (1) lack of participant input on system design; (2) potential underutilization; and (3) challenges to IRB neutrality and resources for dispute resolution. This Part will conclude with a set of recommendations to improve on existing practices.

1. Exclusion of Participants from System Design

The origins of IRBs' IDR systems are largely stories of "muddling through."¹²⁵ Across all institutions, IDR processes arose informally as a set of departmental practices when IRBs responded to unexpected complaints, and those practices were responsive to institutional resources and IRBs' perceived role. At some institutions, practices for complaint resolution remain informal, and even unwritten. Other institutions have codified their practices, but most did not do so until prompted by the AAHRPP accreditation process. Where IRBs consulted external resources during process development, they were likely to ask other IRBs for guidance, rather than developing a new process with input from institutional and external stakeholders. IRBs typically described small modifications over time in response to institutional constraints and learning, but few to none had undertaken a wholesale examination of their complaint resolution practices. As noted above, AAHRPP requires a written policy for the resolution of complaints, but does not set requirements for how these systems are designed and operated.

In light of these origins, all the IDR systems in this Article were uniformly designed without the input of participant representatives. Literature on dispute system design emphasizes the importance of involving all stakeholders—all those who are "affected either by the problem/conflict or by a potential solution."¹²⁶ This can allow dispute system designers to account for parties' interests in process design, and to build in elements of procedural justice from the earliest opportunity.¹²⁷ The informal nature of procedure development clarifies why this has not happened, but it is plausible, ethical, and practical for IRBs to remedy the issue when there is an opportunity to reconsider their current policies.

Two factors may mitigate the exclusion of participants from the development of these IDR processes, but these are incomplete remedies for non-consultation. First, some might classify the IRB itself as a participant representative—it is, after all, bound to ensure the protection of research subjects. But IRBs are composed of members who are dissimilar, in most ways, from research participants. Per the Common Rule, IRBs must include at least five members with varying backgrounds, with efforts made to avoid discrimination by race and gender, and must include at least one scientist, one nonscientist, someone from outside the institution, and someone knowledgeable about applicable laws and standards

¹²⁵ See Charles E. Lindblom, *The Science of "Muddling Through,"* 19 PUB. ADMIN. REV. 79 (1959).

¹²⁶ NANCY H. RODGERS, ROBERT C. BORDONE, FRANK E.A. SANDER & CRAIG A. MCEWEN, *DESIGNING SYSTEMS AND PROCESSES FOR MANAGING DISPUTES* 72 (2013).

¹²⁷ *Id.*, at 75.

of professional practice.¹²⁸ IRBs reviewing research with vulnerable populations (e.g., children, pregnant women, prisoners, people with mental disabilities) must also include individuals who are “knowledgeable and experienced” in working with these groups.¹²⁹ Experience in working with subjects, however, does not mean that IRBs understand how participants may experience research complaints, nor how they would prefer to seek redress at the institution. Moreover, many IDR procedures have developed within IRB administrative offices, rather than being considered by the full IRB.

Secondly, IRBs give participants some say over procedural options, such as electing anonymity, choosing between mediation or an arbitration-like process, or bringing disputes to a trusted local authority for protocols that have provided that choice. Giving participants choices at the time of the dispute alleviates the problem of non-consultation at the outset. But participant feedback is nonetheless important at the time of system design. Having a say in process development is important in part as a matter of procedural justice, but also as a matter of improving system accessibility, the durability of resolutions, and perceived legitimacy of the process (and the research institution more generally).

Consulting participant groups is daunting and complex. Institutions have enormous research portfolios, and it is impossible to consult a representative from every participant constituency. Research changes over time, and current participants may not be well-placed to represent future participants’ needs. The difficulty of incorporating participant perspectives may be one reason why these views are so frequently omitted from general discussions of research ethics.¹³⁰ Part V will consider potential pragmatic strategies for soliciting participants’ views of the dispute resolution system, as well as outcomes that IRBs should consider in evaluating whether system changes have led to improvement.¹³¹

2. *Process Underutilization*

It is difficult to know what an “optimal” number of participant complaints may be. We do not know the frequency of actual or experienced misconduct in research, nor do we know the frequency of physical injury. Moreover, we do not know the number of complaints that participants would deem sufficiently serious to seek resolution, rather than lumping or dismissing the problem. Of this number, we also do not know how many complaints are already addressed by investigators and their staffs, without escalating to the level of an IRB report. If the number of complaints made to IRBs rose sharply, it may be practically impossible for existing institutions to resolve each complaint with the full complement of processes described here—intake, consultation, fact-finding, deliberation, decision, and appeal. Substituting an abbreviated process for the sake of inefficiency could disadvantage complainants with more complex grievances; at the other end of the spectrum, scaling up dispute resolution resources to handle large numbers of complaints may divert resources that are currently used for other ends, such as medical treatment or research expenses. Without knowing the number of complaints that participants may have in aggregate—including those never brought to the IRB’s attention—it is difficult if not impossible to measure important system outcomes such as participant access and uptake.

¹²⁸ 45 C.F.R. § 46.107 (2017).

¹²⁹ *Id.*

¹³⁰ DRESSER, *supra* note 11.

¹³¹ See Section V.A.

It is possible to argue that the number of complaints currently received by IRB dispute resolution systems is in fact optimal. But almost all the informants in this study believed that their processes were underutilized. Prior research on participant comprehension of research protocols at the time of informed consent suggests that there are frequent disparities between participants' expectations and the reality of clinical trials.¹³² For example, research on the "therapeutic misconception" and "preventive misconception" shows that as much as 62% of participants may be expected to believe that medications are effective or have "unrealistic beliefs" about the likelihood of benefit, when those drugs are in fact unproven.¹³³ This is one example of experiences that may not match expectations; many other surprises and misadventures are possible. The numbers in Table 2 may also give us pause to reconsider utilization; a median complaint frequency of 2.2 per 1,000 protocols (which enroll far more than 1,000 subjects!) seems far lower than what might be expected.

Considering these facts, it is reasonable to believe that utilization of these IDR programs is low. Although low uptake may be immediately advantageous for institutions with limited human resources on their IRBs, leaving research-related disputes unresolved can expose research institutions to adverse consequences such as future litigation, future media exposure, poor reputation, and increased costs of future research.

Some of the causes of low system uptake may be difficult to remedy in health care systems that merge therapeutic research with clinical care. Subjects may not wish to jeopardize their care relationships by complaining about studies conducted by their own clinicians. Subjects in all institutions and all types of protocols may also be skeptical of the neutrality of any forum offered by the institution, including the IRB itself, and past research abuses have created a legacy of institutional mistrust in many communities. The dispute resolution systems in this case study were designed exclusively by the institutions, and although subjects could select their desired level of involvement in the process, the institutions did not consult subjects or subject groups during the initial design stage. These barriers may persist regardless of dispute system design, even with an external third-party neutral and advance notice of procedural protections such as the ability to remain anonymous.

But low uptake also reflects a lack of information, particularly lack of awareness of the forum and the process for dispute resolution, and systems can seek to remedy these problems by better educating subjects during study enrollment and follow-up. Subjects' awareness and understanding of protocols and "subjects' rights"—and thus, their expectations of how they should be treated—will inform whether they recognize wrongs as actionable. More effective education about protocol design and clear enunciation of other interests—such as a right to be treated with dignity during the study, or a right to

¹³² See Flory & Emanuel, *supra* note 7, at 1593 (citing studies, including one showing that 30% of participants in cancer trials believed that they were receiving a treatment already proven to be the best for their cancer).

¹³³ Paul Appelbaum et al., *Therapeutic Misconception in Clinical Research: Frequency and Risk Factors*, 26 IRB: ETHICS & HUM. RES. 1 (2004); Charles W. Lidz et al., *Therapeutic Misconception and the Appreciation of Risks in Clinical Trials*, 58 SOC. SCI. & MED. 1689 (2004); Alan E. Simon et al., *Preventive Misconception: Its Nature, Presence, and Ethical Implications for Research*, 32 AM. J. PREV. MED. 370 (2007).

voice concerns about study processes—may help. The low uptake almost certainly reflects low subject awareness of IRB oversight, authority over studies, and availability to resolve subject complaints.

Where subjects *do* understand that a forum exists for the resolution of their complaints, they currently have no way of knowing what will happen when they contact that forum. IRBs do not provide advance notice of procedural protections such as anonymity or confidentiality, nor are subjects aware of how the IRB will proceed to address their concerns. Because procedures are so flexible, written processes may be imprecise or absent, and they are not made available to potential subjects in detail. Subjects do not know in advance, for example, that facilitated negotiation is available, that the IRB makes decisions independent of the research team, or that complaints can sometimes lead to changes in institutional policies that may benefit future subjects. A lack of information about the *process*, which in part derives from broad procedural flexibility, may undermine predictability and subjects' perception of control over their complaints.

3. IRB Neutrality and Capacity

As noted throughout this Article, IRBs have several interests that come into conflict when they manage research-related disputes. IRBs are required to prioritize subject welfare (which may disadvantage researchers); they are colleagues of researchers who are repeat players in IRB review (which may disadvantage participants); and they are also members of the institution and aware of institutional interests. Furthermore, IRBs who oversee disputes are also the very institutional representatives who initially approved study protocols to proceed. If disputes escalate to litigation, IRBs themselves may be liable for negligent protocol approval and oversight,¹³⁴ giving them a direct stake in resolving disputes quickly and with minimal institutional exposure. A participant complaint about study procedures may also be viewed as a challenge to IRBs' original determination that the procedures were ethical, which asks IRBs to revisit these initial judgments at the moment of the complaint. This could compromise equality and accountability, despite IRBs' regulatory role and sincere commitment to the interests of the subject. A long history of scholarship vacillates between two poles: some characterize IRBs as intrusive and stifling to researchers,¹³⁵ while others have viewed IRBs as insufficiently protective, overworked, and vulnerable to capture by researchers.¹³⁶ From the view of IRB personnel themselves, this study suggests sincere efforts at neutrality, but informants acknowledged that multiple interests—and the salience of institutional interests in particular—made this challenging.

The lack of neutrality of a third-party decision-maker can be inimical to all process

¹³⁴ Mello et al., *supra* note 19.

¹³⁵ Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271 (2004); Philip Hamburger, *Getting Permission*, 101 NW. U.L. REV. 405 (2007).

¹³⁶ Hazel Glenn Beh, *The Role of Institutional Review Boards in Protecting Human Subjects: Are We Really Ready To Fix a Broken System?*, 26 L. & PSYCHOL. REV. 1 (2002); Donna Shalala, *Protecting Research Subjects – What Must Be Done*, 343 N. ENG. J. MED. 808 (2000); Ezekiel J. Emanuel et al., *Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals*, 141 ANNALS INTERNAL MED. 282 (2004).

values in dispute resolution,¹³⁷ including participation, accountability, and legitimacy. Participants skeptical of neutrality may decline to use IDR processes, or they may disengage if their experience with the process does not fulfill their expectations of fairness. Neutrality problems can also impair accountability if the decision-maker favors one disputing party, either due to conscious or unconscious bias. A lack of neutrality can also impair legitimacy, if disputing parties do not accept the process or the outcome as fair; this can challenge the durability of resolutions and lead to more disengagement from the process over time. Importantly, however, although these are potential problems, we do not have evidence yet that they are occurring. The study in this Article conducted interviews with IRBs themselves, rather than disputing parties. The broader literature on complaints in human subjects research is also thin, and although there are many records of researcher discontent with IRB decisions (particularly on protocol approval and disapprovals), there is little evidence specific to the participant complaint context.

There are also compelling advantages to using IRBs to manage research-related disputes. IRBs have enforceable authority to suspend research protocols, to require revisions or remedies internal to research protocols, or to cancel protocols entirely, IRBs already have the scientific expertise to understand protocols and potential deviations, and they are familiar with each of the protocols from which disputes arise. IRBs' regulatory role may partially mitigate the lack of neutrality from the participant perspective (although not from the researcher perspective). IRBs within the institution can quickly mobilize other institutional actors, such as department chairs, legal counsel, human resources, and compliance departments that may assist in fact-finding. Moreover, their institutional role as the guardian of participant welfare means that IRBs should be involved, somehow, in any IDR process for research-related disputes. In light of the low frequency of complaints, institutions may also find it inefficient to invest in a separate IDR process for research-related disputes.

The balance of advantages and disadvantages may shift somewhat in multi-site studies under the 2018 revisions to the Common Rule, which requires that multi-site studies use a single IRB of record.¹³⁸ For these studies, the IRB that approved the study may be at a different institution from where the complaint arises. Presumably, these studies could refer complaints either to the local IRB at their site, or to the IRB of record. Local IRB may be somewhat less familiar with study procedures, but they may also have less concern for their own interest (in the event that the dispute escalates to litigation involving the approving IRB). Referring all complaints to the IRB of record presents other advantages, such as familiarity with the protocol and potentially less concern about liability of their own research institution. The revised Common Rule does not specify how complaints or injuries arising from such study should be resolved, leaving this an open question.¹³⁹

Without evidence of current harm, and given the structural advantages of using IRBs for resolving research-related complaints, it is sensible to leave these dispute resolution processes within the IRB. But this raises questions of institutional support and IRB training for dispute resolution tasks. Informants in this study described burdens in implementing the IDR process, including substantial human resources, time necessary for deliberation on

¹³⁷ Redish & Marshall, *supra* note 37

¹³⁸ 82 Fed. Reg. 7149 (Jan. 19, 2017).

¹³⁹ Stark & Greene, *Clinical Trials*, *supra* note 72 (noting that centralized IRB review raises questions about allocating institutional liability).

both process and outcome, emotional strain and fatigue, and a lack of skills training in relevant areas such as mediation or conflict resolution. IRBs are already (and have long been) overtaxed in time and resources, and they navigate an increasingly complex set of federal, state, and institutional policies. Particularly if the number of complaints were to increase, IRBs currently lack some expertise and resources needed for an effective response to complex or emotionally fraught complaints.

This discussion raises the question of IRBs' capacity and motivation to make changes to their IDR systems. To that end, IRBs have some advantages that make them well-positioned to improve these processes. Human research protection programs are fairly small and self-contained within their institutions, and they have a great deal of discretion over their internal procedures and their interpretations of federal regulations. IRBs or the heads of human research protection programs often report directly to institutional presidents or vice presidents for research, and IRBs' independent federal mandate to protect research participants gives them a separate source of authority to make changes that they deem necessary for that goal. IRB chairs and administrative staff are extremely well educated, as noted in this study, and they are attentive to their federal mandate, as this study has suggested. The informants in this study often expressed the motivation to improve their processes, including asking about other institutions' best practices, and many noted that this was the first time they had the opportunity to reflect on this institutional function. In their institutional capacity, moreover, these informants had power to make or credibly suggest changes to existing policies. It appears, therefore, that there would be high capacity and perhaps high motivation to change these systems given awareness of the need. But to date, IRBs have experienced a low frequency of complaints, creating few opportunities to reconsider their processes or to evaluate their effectiveness. IRBs also may lack the time, financial resources, and manpower to study this issue or to make resource-intensive changes. Some of the suggestions below, such as compensating injured participants, may be beyond the power of the IRB, and more properly suggested to institutional presidents or general counsels. But where changes are inexpensive and fairly straightforward, there is good reason for optimism about IRBs' capacity and motivation to improve their IDR processes.

V. IMPROVING IDR FOR RESEARCH-RELATED INJURIES

The previous Part describes a number of drawbacks of current IDR processes for resolving research-related disputes. This Part will conclude with recommendations for improving the functioning and fairness of these dispute resolution systems.

As noted above, I stop short of recommending that these IDR systems be relocated outside the IRB. To be sure, the Department of Health and Human Services and the FDA could *require* the use of a neutral third-party mediator or arbitrator through the federal regulations governing human subjects research. This could also be achieved by federal or state statute, by professional accreditation standards set by AAHRPP, or by changes in institution-level policies. But the costs of this choice may well outweigh the gains for most disputes, particularly those that do not allege physical injury or a legal claim against the institution (and even for these claims, the use of a neutral third party may still pose the problem of the institution as a repeat player).¹⁴⁰ The structural advantages of having IRBs

¹⁴⁰ Galanter, *supra* note 12.

involved in dispute resolution for research-related injuries are great, and although non-neutrality is problematic, it is inherent to all IDR systems, and it is partially offset (from the subject perspective) by the IRB mandate to protect subjects. Imposing the requirement of a third-party neutral from outside the institution would also scale up the costs of disputes and could impose inefficient levels of process for minor complaints. Requiring subjects to bear these costs would impair access to the forum, as most subjects would be unable or unwilling to pay. Institutions could bear the costs, but this may impair neutrality of the forum for third-party decision-makers that were repeatedly retained. Requiring research sponsors to bear the costs would increase the expense of research more generally, posing tradeoffs between paying for more research or more administrative costs.

I will also stop short of recommending changes to the Common Rule to structure or constrain IDR as implemented by IRBs. This is for a similar reason; although we now have evidence from IRBs about how their processes currently work, including some likely deficiencies, we do not have systemic evidence that these deficiencies are experienced by subjects or researchers as harmful. IRBs described uses of procedural flexibility in order to promote participant priorities, such as voice and access. Mandating and monitoring IRB compliance with new regulatory requirements for complaint resolution, especially when the frequency of complaints may be low, is likely to increase inefficiencies in the current system. It may also discourage innovation, such as institutions that began using local trusted authorities in culturally or linguistically distinct participant populations to assist in handling disputes. Changing federal regulations may also not be necessary to improve IDR practices in IRBs; there are numerous examples of internal changes in IRBs that did not require a regulatory nudge.¹⁴¹ Interviews with these informants suggested that many institutions were open to guidance and an opportunity to revisit their IDR procedures, and the informal nature of many of these IDR systems may facilitate the incorporation of new ideas without a regulatory requirement.

A. Consult Research Participants During System Design

First, IRBs should make efforts to consult participants at the moment of system design, or during periodic reevaluation of procedures. As noted above, this is not entirely straightforward, given that institutions often have many thousands of research portfolios representing a large number of different participant groups.

As a practical matter, consultation of participants' perspectives on dispute system design could either occur on a protocol-by-protocol basis or at the level of the IRB. On a per-protocol basis, IRBs could ask researchers to consult with representatives from participants or the larger community—such as through the use of a community advisory board¹⁴²—to ascertain participant preferences for dispute resolution in the individual study. Or similarly, IRBs could ask researchers to disclose more information about the dispute

¹⁴¹ Stark, Victims, *supra* note 72 (citing examples).

¹⁴² A community advisory board (CAB) is a small group of community stakeholders in a research project that provides meaningful input on the design and implementation of a research protocol. See, e.g., Stephen F. Morin et al., *Community Consultation in HIV Prevention Research: A Study of Community Advisory Boards at 6 Research Sites*, 33 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 513 (2003); Sandra Crouse Quinn, *Protecting Human Subjects: The Role of Community Advisory Boards*, 6 AM. J. PUBLIC HEALTH 918 (2004).

resolution process, and to ask for informal feedback at the time of informed consent or the conclusion of studies.¹⁴³ Researchers could then report this information in aggregate back to the IRB for consideration. Another strategy may be for institutions to randomly select a small number of ongoing protocols and invite subjects enrolled in these protocols to give feedback on the dispute resolution procedure at the time of informed consent.

At the level of the IRB, the easiest (and least representative) method for soliciting feedback on the IDR system would be to ask participants for feedback while they are using the process, or perhaps after their issue is resolved. This may yield a biased perspective, however, because it will only capture the views of participants who have already chosen to use the system in its current form. IRBs could collect more representative feedback by soliciting comments from all participants in approved protocols at a given point in time—such as by allowing anonymous comments through a web portal, using a process akin to notice-and-comment rulemaking, or a series of public meetings.¹⁴⁴ Researchers could publicize this comment process to their current research participants. Or IRBs could prospectively identify the most common participant populations in their approved studies, and conduct focus groups sampling from these groups. This would be the most resource-intensive option, however, and it would likely be beyond the capacity of most IRBs.

The opportunity for subject participation in the design of these IDR processes may assist in improving access, procedural options, participation, and perceived legitimacy of the process. Where comments suggest potential improvements, IRBs could make provisional changes to their policies and assess the impact of these changes. These impacts should include outcomes such as complaint type and frequency, participant satisfaction, perceived legitimacy of the process, participants' perception of the institution's accountability during research, and participant awareness of the dispute resolution forum.

B. Increase Disclosure and Involve Participant Community Leaders

Second, IRBs should consider a range of other options to increase uptake and process utilization by participants. Although as a practical matter, no IRB wants to add to its workload, the informants in this study were convinced that low complaint frequencies indicated a problem with awareness and access. The remedy for lack of awareness is, of course, disclosure. IRBs can publicize their IDR processes on their websites, but it would be more useful to disclose more information at the time of informed consent. Several issues complicate disclosure. First, when processes are highly informal or malleable, there may be no formulate procedure to publicize; IRBs may therefore choose to highlight several process options, such as the option to make an anonymous complaint or the option of having an IRB staff member mediate communication with the investigator. Next, most investigators know little about the complaint resolution process, which means that institutions must educate not only subjects, but also investigators about this IRB function.

¹⁴³ Another strategy would be to require a representative for particular participant groups to be on the IRB, as is currently done for research with prisoners, 45 C.F.R. § 46.304(b)—but this may be more burdensome in practice

¹⁴⁴ Gathering these data would not count as “research” for IRB purposes, because it is not intended to contribute to “generalizable knowledge”—it would be solely for the purposes of improving internal operations. 45 C.F.R. § 46.102(d).

Furthermore, adding elements to informed consent is not costless. Informed consent forms can be long and complex, and proposed changes to the Common Rule reflect some of these problems.¹⁴⁵ Adding information about dispute resolution systems can compete for subject attention and extend the duration and complexity of the informed consent process. It may also attune participants to the possibility that they *could* be harmed, which could hinder enrollment or increase mistrust. But this is unlikely to be a substantial barrier; according to a recent study, even when participants are aware of the *death* of a healthy subject at the same institution, only 17% said this changed their thoughts about joining research, and only 4% said it would change their future participation.¹⁴⁶

None of these drawbacks should hinder greater disclosure of institutions' processes for resolving research-related complaints. Meaningful consent to research must be predicated on "essential information that a reasonable person would want to know in order to make an informed decision about whether to participate"¹⁴⁷—and the availability and quality of a forum to resolve research-related disputes and injuries may be essential for many participants. IRBs could potentially improve the effectiveness of these disclosures by asking investigators to convey this information verbally. Several reviews of informed consent strategies have shown that verbal disclosure and discussion is the most effective means of communicating with research participants,¹⁴⁸ and this would be an appropriate and efficient means of disclosing subjects' options in the event that complaints arise.

Another strategy for increasing process uptake may be to use a practice that several institutions have pioneered: asking investigators to identify a trusted member of the community to receive complaints and represent participant interests in communicating them to the IRB. Several institutions reported using trusted local authorities to help process complaints in research with distinctive populations, such as Native American tribes. One advantage of this process is that it outsources part of the responsibility to investigators to build stronger relationships with local subject communities; investigators must identify someone who can be familiar with the protocol and accept complaints, and then convey those complaints to the investigator or to the IRB. Investigators can then disclose this information to subjects as part of the informed consent process. Of course, subjects should keep the ability to complain to the IRB directly, in case the trusted local authority is unfamiliar or an inappropriate resource for them personally. But this may have additional benefits of improving investigators' engagement with participant populations, while also increasing the accessibility of the process to subjects. Another variation on this theme may be to add a member of the participant population as a temporary consultant to the IRB during deliberations about subject complaints arising from that protocol.

C. Compensate Participants for Physical Injuries

The informants in the study who expressed the greatest comfort with their IDR processes were at institutions that had agreed—either explicitly or as a de facto matter—to compensate participants for physical injuries sustained during human subjects research.

¹⁴⁵ 80 Fed. Reg. 53970 (Sept. 8, 2015).

¹⁴⁶ Caitlin E. Kennedy et al., *When a Serious Adverse Event in Research Occurs, How Do Other Volunteers React?*, 6 J. EMPIRICAL RES. HUM. RES. ETHICS 47 (2011).

¹⁴⁷ 82 Fed. Reg. 7149 (Jan. 19, 2017).

¹⁴⁸ Flory & Emanuel, *supra* note 7; Nishimura et al., *supra* note 7.

There have been repeated calls and detailed proposals for U.S. research institutions to compensate participants for injuries, but this is not yet federally required.¹⁴⁹ Indeed, the NIH does not compensate participants for injuries, and there is no requirement that U.S. research institutions carry insurance for this purpose.¹⁵⁰ Many institutions had an unwritten practice of compensating injured participants, often by providing treatment themselves (e.g., at their own hospital) and waiving participant costs or cost-sharing. But nearly half of the institutions had a policy of never compensating subjects for physical injury (17%), or only compensating subjects when the research funders would agree to it up front (30%).

Compensation policies clearly facilitate dispute resolution of research-related complaints. IRB personnel who knew that their institution would ultimately pay participants for injuries sustained reported far greater confidence in managing disputes, less defensiveness, less concern about institutional liability and escalation of the dispute, and a greater sense that the system was operating ethically under Belmont Report principles for protecting human subjects. Although compensation was rarely if ever offered for non-physical injury, allowing compensation in cases of tangible harm was viewed as an essential procedural option. Informants at institutions that disallowed payments for injuries noted their frustration with this practice, and some commented that they wish their institution would institute more flexible policies.

This Article therefore echoes prior calls for institutions to compensate participants for tangible injuries sustained over the course of research, either by self-funding or purchasing insurance for this purpose. In addition to the ethical rationale for paying for research harms, allowing these payments has a highly pragmatic function of facilitating all dispute resolution in this context.

D. Build IRB Capacity for Conflict Resolution

The previous Part outlined some of the deficiencies of IRBs in expertise and resources for conflict resolution. The remedy is straightforward. In order to improve IDR processes—or to continue current processes in the event that process uptake increases—research institutions may need to devote additional personnel and training to IRB offices, or add administrative staff members who have prior training in conflict resolution. Very few of the personnel responsible for resolving complaints had training in dispute resolution; approximately 6% were trained as J.D.s, but even informants with law degrees noted that they lacked training on the interpersonal elements of conflict resolution or ADR. Research institutions could help meet these expertise needs by running workshops for IRB personnel—particularly managers and administrators, rather than members—or by considering conflict resolution training during hiring. Another method of increasing this expertise is to add modules to the Certified IRB Professional (C.I.P.) course run by the Council for Certification of IRB Professionals. More than 50% of informants in the study had obtained this qualification, suggesting that training modules on conflict management would be a good means of disseminating this information. Although AAHRPP accreditation was frequently described as complex and somewhat burdensome, an AAHRPP recommendation of having conflict resolution training would be another means of encouraging expertise-building among IRBs.

¹⁴⁹ Pike, *supra* note 5; Elliott, *supra* note 19.

¹⁵⁰ *Id.*

Human resources may be another need—again, particularly if the frequency of complaints increases. Complex complaints, although rare, were highly resource-intensive for IRB personnel. Many have called on research institutions to invest more in IRBs, and in human resource protection programs more generally, to improve the speed and quality of protocol review. Improving IRB responses to participant complaints may be another reason to expand this area of the institution, if the frequency or complexity of complaints increases.

E. Use Records Effectively

IRBs can also improve their IDR systems through their practices for record-keeping and systematic examination of those records over time. Many IRBs did not record complaints in a manner that would allow for comparison across protocols, or over time. Making these comparisons at regular intervals, such as one- or two-year periods, could help IRBs identify recurring issues; they could address these through investigator training and protocol review instead of piecemeal responses to complaints. Creating a way to view complaints together would also improve institutional memory and consistency, particularly at times of personnel turnover, which may be essential for highly informal processes. IRBs are sensitive to local precedent,¹⁵¹ and they may welcome opportunities to ensure that their responses to subject issues are consistent over time.

F. Provide for (Advisory) Third-Party Review

Instead of requiring the use of a third-party neutral for the initial resolution of every complaint, it may be more feasible and efficient to provide for appeals to an external reviewer or internal ombudsman to review IRBs' final decisions about complaints. At present, IRBs usually give investigators a written decision once a complaint is resolved. Investigators have an opportunity to appeal for reconsideration, but IRBs typically do not give or publicize to participants the possibility of an appeal. In some ways this lopsided procedure makes intuitive sense; IRBs can sanction investigators, but not participants, as part of the resolution, so investigators may make more use of this appeal mechanism. But from the participant's perspective, someone dissatisfied with the IRB's decision may feel that they have experienced harm without remedy, and some may want the same appeal option to demonstrate that they are being treated equally in the process.

An IRB could, therefore, address both concerns about neutrality and lopsided appeals by providing for an independent reviewer, which could be requested by the investigator, the participant, or even perhaps by the IRB itself if they seek a second opinion or fear institutional interference. This could function similarly to the external review mandated by state and federal law for coverage disputes in private health insurance, but would likely be far smaller in scope.¹⁵² Given IRBs' current goal of subject satisfaction with the process—and their view that most participants are in fact satisfied—the uptake (and therefore costs) of this external review are likely to be fairly low. Institutions could

¹⁵¹ STARK, *supra* note 72

¹⁵² Hunter, *supra* note 32.

collaborate with one another to develop the infrastructure for this independent reviewer—for example, research institutions in each state could contribute to the costs of maintaining an ad hoc independent external reviewer for the state or region. When a subject or researcher invokes independent review, the IRB would then send the reviewer any reports of the complaint investigation and decision for their independent analysis and written opinion.

Although this independent review process may resemble the process of external review for health insurance coverage decisions, the process will necessarily be weaker. In external review for health insurance coverage disputes, the decision of the external review process is binding on the insurance company. But for structural reasons, binding external review is complex and likely not viable here. The federal regulations delegate authority for research protocol approval, disapproval, and oversight to IRBs; the rules specifically provide that research “may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.”¹⁵³ The Common Rule does not permit institutions to delegate this authority outside the IRB (although using an external, paid IRB that is subject to federal regulation is permitted). Moreover, if the reviewer were an ombudsman within the institution, he or she could require *more stringent* protocol restrictions or termination, but could not *lift* protocol restrictions or reverse a study termination required by the IRB. This would make binding review of little use to investigators facing sanctions. Some complaints may also raise issues outside the IRB’s purview, such as complaints of investigator harassment, which are typically referred to human resources and handled as legal matters.

For this reason, *binding* review by an independent party, or even binding review by an internal ombudsman who is not part of the IRB, is likely unavailable here; review will be advisory rather than binding. But even an *advisory* review of IRB decisions would be useful in alleviating concerns about neutrality and the inequality of the current appeals process. IRBs will have the opportunity to reconsider their findings in light of the third-party reviewer’s recommendation, and then to adjust any protocol sanctions or remedies provided. The availability of a third-party advisory review may also shape IRBs’ actions even when it is not invoked. IRBs that know a third party will evaluate their decision may take greater care in their analysis and written decisions, and they may produce (and subsequently use) better records of their process. All of these changes may help produce fairer and more effective decision-making throughout the dispute resolution process.

VI. CONCLUSION

The empirical study in this Article was the first in-depth look at the highly flexible systems that research institutions have established to mediate and, at times, adjudicate disputes involving human subjects. Disputes in this area are characterized in part by high stakes for investigators and institutional exposure to liability, but also by disparities in socioeconomic power and sophistication between participants and research institutions. Attention to fair process is therefore an ethical and practical imperative for functioning systems. At present, institutions’ IDR systems take advantage of IRBs’ mandate and authority to protect subjects, and IRBs have instituted highly flexible procedures to

¹⁵³ 45 C.F.R. § 46.112 (2017)

maximize the voice and satisfaction of research subjects who bring grievances. But notwithstanding these strengths, IDR systems for research-related complaints also pose problems of inclusion, access, neutrality, resources, and expertise. Changes to the Common Rule, such as the requirement that multisite studies designate one IRB of record, may continue to bring changes to how research-related disputes are resolved.

In light of these findings, this Article has recommended a number of structural changes to how IRBs handle research-related grievances. These include suggestions for considering participant input on system design; increasing publicity and accessibility through informed consent procedures and integration of participant community leaders; compensating participants for physical injuries; building IRB expertise and resources for conflict resolution; using records to identify recurring complaints and improve consistency; and providing for advisory third-party review and reconsideration of decisions, even if that review is not binding. Institutions dedicated to protecting the welfare of human subjects may well make these changes without being prompted by a change in federal or state regulations; with the exception of the suggestion that institutions compensate injured participants (which has repeatedly been ignored), these ideas build on existing systems and do not require large resource outlays. The practical rewards of a functioning IDR system may be great, including reduced institutional exposure, improved community relations, and increased legitimacy of research at the institution. But most importantly, these adjustments to IDR processes for research-related harms are ethically warranted. The Belmont Report and other ethical guidelines have spoken widely on the need to minimizing subject harm, but have said little about how institutions can (and should) offer redress when they fail to do. Participants in human subjects research take on many burdens in the interests of scientific progress; when they experience unintended harms, they should not bear the additional burden of unfair process. This Article is a start toward that goal.

TABLE 1. CHARACTERISTICS OF INDIVIDUAL RESPONDENTS

Characteristic	Percentage (n = 31)
Position	
Director	77%
Manager	13%
Chair or Administrative Chair	6%
Administrator	3%
Gender	
Female	74%
Male	26%
Median Time in Current Position	4.5 years (range 0.25-25 years)
Median Time in Research Protections	12 years (range 2-25 years)
Median Time Managing Complaints	9 years (range 1-25 years)
Highest Degree	
B.A./B.S.	16%
M.A./M.S.	39%
J.D.	6%
M.B.A.	10%
Ph.D./M.D.	29%
Certified IRB Professional (C.I.P.) Qualification	
Currently Certified	42%
Previously Certified	10%
Lapsed	32%
Not Known	16%

TABLE 2. CHARACTERISTICS OF INSTITUTIONS

Characteristic	Percentage (n = 30)
Type of Institution	
University with Affiliated Hospital	67%
University without Hospital	13%
Hospital	20%
U.S. Census Region	
Northeast	40%
West	23%
South	20%
Midwest	13%
Other	3%
AAHRPP Accreditation	
Current	50%
Pending	10%
Not Accredited	37%
Not Known	3%
Median Active Protocols	2,000 (range 20-5,000)
Median Annual Complaints per 1,000 protocols	2.2 (range 0-43.5)
Written Policy or Procedure for Complaint Resolution	73%
Previously Experienced Litigation Involving Human Subjects	30%
Policy for Compensating Subjects for Physical Injury	
Compensated Some or All Injuries	47%
Compensated Depending on Sponsor Agreements	30%
Never Compensated	17%
Uncertain	7%