

## Human Subjects Research Review: Scholarly Needs and Service Opportunities\*

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*Academic law libraries have evolved to support new forms of legal research and instruction. Attendant to the rise in empirical legal research, law libraries could provide human subjects research review services. These interesting and value-added offerings leverage librarians' regulatory analysis skills and contribute valuably to the campus research community.*

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### Introduction

¶1 Legal scholarship has been evolving for decades. While doctrinal analyses still dominate academic law reviews, law faculty are increasingly undertaking complex interdisciplinary research.<sup>1</sup> Law librarians have witnessed “a growing diversity

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1. Margaret Butler, *Law Library Faculty Services Web Sites: Effectively Communicating Services Provided for Faculty*, 31 LEGAL REFERENCE SERVS. Q. 239, 239 (2012); Robert C. Ellickson, *Trends in Legal Scholarship: A Statistical Study*, 29 J. LEGAL STUD. 517 (2000). Admittedly, the “normative doctrinal”/“complex interdisciplinary” dichotomy is crude. For more subtle distinctions, see Richard A. Posner, *The Present Situation in Legal Scholarship*, 90 YALE L.J. 1113 (1981).

in the nature of legal scholarship” for many years.<sup>2</sup> This difference might be more a matter of degree than kind, as law professors have long incorporated ideas from other disciplines and empirical data into their work.<sup>3</sup> Still, the scholarly portfolios of many law school professors—and student researchers—seem to have diversified in recent years. Concomitantly, legal education and research support services have expanded.

¶2 For a while, law faculty have been experimenting with “new forms of interdisciplinary legal education.”<sup>4</sup> They have deployed anthropological methods of teaching professional responsibility,<sup>5</sup> employed students in verifying crime statistics,<sup>6</sup> engaged emerging scholars in challenging unscientific legal studies,<sup>7</sup> and mentored students through the process of drafting social science study designs.<sup>8</sup> A number of law schools have launched working groups and centers that immerse students in public policy and data-intensive clinical work,<sup>9</sup> some of which requires information-gathering from clients and community members, or “human subjects” in social science parlance.

¶3 The topic of human subjects research has appeared in prominent empirical legal studies textbooks, though sparse attention has been paid to navigating human

2. Sheri H. Lewis, *A Three-Tiered Approach to Faculty Services Librarianship in the Law School Environment*, 94 LAW LIBR. J. 89, 91, 2002 LAW LIBR. J. 5, ¶8; see also Albert Brecht, *Changes in Legal Scholarship and Their Impact on Law School Library Reference Services*, 77 LAW LIBR. J. 157 (1984–1985).

3. Lee Epstein & Gary King, *The Rules of Inference*, 69 U. CHI. L. REV. 1, 1 (2002); see also N.E.H. Hull, *Some Realism About the Llewellyn-Pound Exchange over Realism: The Newly Uncovered Private Correspondence, 1927–1931*, 1987 WIS. L. REV. 921. See, e.g., a report produced by the interdisciplinary Institute of Law at the John Hopkins University: LEON C. MARSHALL, *COMPARATIVE JUDICIAL CRIMINAL STATISTICS: SIX STATES, 1931*, at 1 (1932) (“These pages [report research] brought back from the courts of general criminal jurisdiction of six states a record of happenings to some 45,265 defendants whose cases were filed in 1931.”). That Institute was created for the social scientific study of law. COMMITTEE ON ORGANIZATION, *THE STORY OF THE INSTITUTE OF LAW AT JOHN HOPKINS UNIVERSITY* 10 (1929).

4. Elizabeth E. Mertz, *Social Science and the Intellectual Apprenticeship: Moving the Scholarly Mission of Law Schools Forward*, 17 LEGAL WRITING 1, 15 (2011). See also Justice Sonia Sotomayor’s fond recollection of Guido Calabresi’s interdisciplinary torts class at Yale Law School in the late 1970s. SONIA SOTOMAYOR, *MY BELOVED WORLD* 173 (2013).

5. Elizabeth Chambliss, *Professional Responsibility: Lawyers, A Case Study*, 69 FORDHAM L. REV. 817, 822 (2000).

6. *Clinic Students Reveal Crime Data Discrepancy*, UNIV. OF CHI. LAW SCH. (Nov. 18, 2014), <http://www.law.uchicago.edu/news/clinic-students-reveal-crime-data-discrepancy> [<https://perma.cc/G62R-HV6W>].

7. Elizabeth Warren, *The Market for Data: The Changing Role of Social Sciences in Shaping the Law*, 2002 WIS. L. REV. 1, 42 (“Everyone in this room should care about the developments I have described. Your Congress, your state legislature, your city council, your fellow citizens, and you will be affected by data and pseudo-data in all manner of public policy debates.”).

8. For example, in the courses *Introduction to Empirical Legal Research* and *Empirical Legal Research*, taught by Sarah E. Ryan and Scott Matheson at Yale Law School. See *Empirical Legal Research*, YLS: COURSES, <https://courses.law.yale.edu/courses/Course/898> [<https://perma.cc/HLV5-W6NP>].

9. See, e.g., *About the Center*, CENTER ON LAW, EQUALITY AND RACE, UC, IRVINE SCH. OF LAW, <http://www.law.uci.edu/academics/centers/clear/> [<https://perma.cc/3E77-G38V>]; *Empirical Research Group*, UCLA LAW, <https://law.ucla.edu/centers/interdisciplinary-studies/empirical-research-group> [<https://perma.cc/76Z7-ZKHS>]; *Justice Collaboratory*, YALE LAW SCH., <http://www.law.yale.edu/intellectuallife/tjc.htm> [<https://perma.cc/9BH9-J55F>]. Many law schools have involved legal clinic students in social science analysis and policy report writing. See, e.g., *Law Clinics Release Report on State’s Children Serving Long Prison Sentences*, QUINNIPIAC UNIV. (Mar. 12, 2013), <https://www.qu.edu/news-and-events/law-clinics-at-quinnipiac-and-yale-release-report-on-state%E2%80%99s-children-serving-long-prison-sentences> [<https://perma.cc/9VJA-SRL3>].

subjects research review boards,<sup>10</sup> nationally known as institutional review boards (IRBs). Notably, one prominent textbook features a portion of a law review article that might mislead law school students and faculty into believing that they do not need to seek IRB approval for most research. The excerpt states: “all research funded by the federal government and involving human subjects [must] be overseen by an IRB.”<sup>11</sup> The passage implies that unfunded or privately funded research need not pass through the university IRB. In practice, nearly all universities opt to apply federal regulations as requiring institutional review of all human subjects research projects conducted by students, faculty and staff—regardless of funding source—if an institution receives *any* federal research funding.<sup>12</sup> The paucity of IRB information in leading empirical legal research textbooks suggests that human research ethics and IRB review processes are potential growth areas for library support.

¶4 As legal scholarship and teaching have evolved, so too have library services. Law libraries have honed existing offerings and launched new programs, particularly for social science research support.<sup>13</sup> For instance, empirical research assistance now ranges from in-house statistical analysis<sup>14</sup> to publishing guidance<sup>15</sup> to data procurement—including the filing of Freedom of Information Act requests for

10. See LEE EPSTEIN & ANDREW D. MARTIN, AN INTRODUCTION TO EMPIRICAL LEGAL RESEARCH 70–81 (2014). Epstein and Martin discuss “Generating Data” via experiments, surveys, and observation, but do not advise readers of the ethics review process they must follow to conduct the research vis-à-vis most universities. See ROBERT M. LAWLESS, JENNIFER K. ROBBENOLT & THOMAS S. ULEN, EMPIRICAL METHODS IN LAW 48–49, 371 (2010). The authors devote several pages to IRBs.

11. LAWLESS, ROBBENOLT & ULEN, *supra* note 10, at 48. The quoted law review article is David A. Hyman, *Institutional Review Boards: Is This the Least Worst We Can Do?*, 101 NW. U. L. REV. 749, 750 (2007).

12. See *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, AM. ASS’N OF UNIV. PROFESSORS (2006), <http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm> [<https://perma.cc/YE99-5655>]. Through Freedom of Information Act (FOIA) requests, the AAUP discovered that “to date, 164 [academic institutions] have explicitly declined to commit themselves to imposing on research that is not federally funded the regulations that govern federally funded research.” Though a noteworthy development, these universities represent less than four percent of degree-granting institutions in the United States or less than six percent of four-year colleges. See *Fast Facts*, NAT’L CTR. FOR EDUC. STATISTICS, <https://nces.ed.gov/fastfacts/display.asp?id=84> [<https://perma.cc/ESC9-RYCX>]. For examples of typical university interpretations of IRB scope, see *Institutional Review Board, Frequently Asked Questions (FAQ)*, CORNELL UNIV., <https://www.irb.cornell.edu/faq> [<https://perma.cc/R5UD-9DA2>] (“Any institution that receives federal funding to conduct research with human participants, such as Cornell University, is required to establish an IRB to review all research that directly or indirectly involves human participants, and to set forth institutional policy governing such research.”); *Summary of Federal Laws*, THE CATHOLIC UNIV. OF AM. OFF. OF GEN. COUNSEL (Oct. 19, 2015), <http://counsel.cua.edu/fedlaw/irb.cfm> [<https://perma.cc/PG8N-F9UN>].

13. Christina Glon, *Faculty Scholarship Support: Empirical Research, Project Management, and Library Services*, AALL SPECTRUM, June 2015, at 17, 18; Teresa M. Miguel-Stearns & Sarah E. Ryan, *The Empirical Research Law Librarian Part I: Making the Case and Filling the Role*, 24 TRENDS L. LIBR. MGMT. & TECH. 1 (2014); Sarah E. Ryan & Teresa M. Miguel-Stearns, *The Empirical Research Law Librarian Part II: Filling the Role*, 24 TRENDS L. LIBR. MGMT. & TECH. 7 (2014).

14. Sarah E. Ryan, *Data, Statistics, or Secondary Statistical Analysis: Helping Students Articulate and Acquire the Numbers They’re (Really) Seeking*, 22 PERSP.: TEACHING LEGAL WRITING & RES. 30 (2013); Ryan & Miguel-Stearns, *supra* note 13, at 8; see also ERC: *Empirical Research Caucus*, AM. ASS’N OF LAW LIBRARIANS, <http://community.aallnet.org/empiricalresearchcaucus/home> [<https://perma.cc/7R62-SQWU>].

15. See Sarah Ryan, *Tracking & Promoting Your Scholarship: Impact Factor Assessment, Submission Strategizing, Research Marketing, and More!*, LILLIAN GOLDMAN LAW LIBRARY (Nov. 14, 2013), <http://library.law.yale.edu/news/tracking-promoting-your-scholarship-impact-factor-assessment-submission-strategizing-research> [<https://perma.cc/9FUC-QF4B>]; *Student Publishing: Empirical Research*, DRAKE LAW, <http://libguides.law.drake.edu/c.php?g=150979&p=992570> (last updated Aug. 3, 2016).

government data.<sup>16</sup> Further, while law libraries continue to offer time-honored services such as interlibrary loan, bibliographic production, database training, and preemption checking,<sup>17</sup> law librarians are increasingly furnishing complementary empirical services such as SSRN and research data management assistance.<sup>18</sup> Innovative services respond to existing researcher challenges, such as the need to work remotely,<sup>19</sup> and anticipate future opportunities and obstacles, such as increased funding in a particular empirical legal studies research area<sup>20</sup> or information loss absent data management education.<sup>21</sup> Similarly, research ethics training and librarian review of research packets submitted to the IRB, known as protocols, address a nascent community research need. Further, as this article will describe, human subjects research support can be a highly visible, low-volume, interesting, and valued addition to existing library services.

¶5 This article will proceed in four parts: (1) the need for human subjects research support services, (2) the four research review designations IRBs employ in classifying empirical research, (3) the research and regulatory work involved in classifying empirical research and reviewing human subjects research protocols, and (4) a conclusion.

## The Need: Criticisms and Realities of Institutional Review Boards (IRBs)

### Researcher Criticisms of IRBs

¶6 For decades, academic researchers have criticized IRBs for being needlessly slow, technocratic,<sup>22</sup> and intrusive.<sup>23</sup> This perception reflects varying degrees of

16. On the FOIA efforts of University of Virginia School of Law librarian Jonathan Ashley, see Ben Protes, *Your Homework Assignment: Sue the Federal Government*, N.Y. TIMES DEALBOOK (Apr. 8, 2014), <http://dealbook.nytimes.com/2014/04/08/your-homework-assignment-sue-the-federal-government/> [https://perma.cc/A8W3-QGYE].

17. See Butler, *supra* note 1, at 251.

18. *Id.* at 255; Glon, *supra* note 13, at 18; see also Sarah Ryan, *Data Management Planning: The New Frontier and Support at Yale*, LILLIAN GOLDMAN LAW LIBRARY (Mar. 21, 2014), <http://library.law.yale.edu/news/data-management-planning-new-frontier-and-support-yale> [https://perma.cc/V6A4-R67R].

19. Julian Aiken & Fred Shapiro, *The Yale Law Library, On Demand: A Holistic Approach to Library Services*, 33 LEGAL REFERENCE SERVS. Q. 226, 238 (2014).

20. On proactive services, see Lewis, *supra* note 2, at 97. For future funding opportunities, see *Law & Social Sciences (LSS)*, NAT'L SCI. FOUND., [https://www.nsf.gov/funding/pgm\\_summ.jsp?pims\\_id=504727](https://www.nsf.gov/funding/pgm_summ.jsp?pims_id=504727) [https://perma.cc/JY42-A4E9].

21. See Jake Carlson et al., *Developing an Understanding of Data Management Education: A Report from the Data Information Literacy Project* [presentation slides] (2013), [http://docs.lib.purdue.edu/lib\\_fspres/11/](http://docs.lib.purdue.edu/lib_fspres/11/).

22. Lura Abbott & Christine Grady, *A Systematic Review of the Empirical Literature Evaluating IRBs: What We Know and What We Still Need to Learn*, 6 J. EMPIRICAL RES. HUM. RES. ETHICS 3, 3 (2011); see also Becky J. Little & Elizabeth W. Brazelton, *Psychology Faculty Satisfaction and Compliance with IRB Procedures*, 18 IRB: ETHICS HUM. RES. 4, 5 (1996); Jerry Menikoff, *Where's the Law? Uncovering the Truth about IRBs and Censorship*, 101 NW. U. L. REV. 791, 799 (2007); Zachary M. Schrag, *The Case Against Ethics Review in the Social Sciences*, 7 RES. ETHICS 120, 120 (2011); George Silberman & Katherine L. Kahn, *Burdens on Research Imposed by Institutional Review Boards: The State of the Evidence and Its Implications for Regulatory Reform*, 89 MILBANK Q. 599, 607 (2011).

23. For a robust debate about whether IRBs are overly intrusive and chill free speech by requiring researchers to gain permission prior to conducting research, see *Symposium: Censorship and Institutional Review Boards*, 101 NW.U.L. REV. 399 (2007).

truth. Empirical studies have demonstrated a heterogeneity of IRB efficiency,<sup>24</sup> and some scholars have concluded that IRB review of social science protocols is routinely, needlessly stringent.<sup>25</sup> But others have documented the competing demands faced by academic IRBs, including industry and university preferences for legalistic research participant consent forms.<sup>26</sup> Still others have credited IRBs with curbing inhumane research, particularly in the biomedical sciences, as they were created to do.<sup>27</sup> Many scholars have acknowledged that researcher mistakes impede timely review,<sup>28</sup> and a number have advocated for presubmission protocol screening to minimize researcher errors and, ultimately, IRB delays.<sup>29</sup> Prescreening and researcher education—particularly student training—could also ease the burden of overworked university IRBs.

### Workloads and Organizational Challenges of University IRBs

¶7 There is near consensus that the workloads of university IRBs have grown in recent decades.<sup>30</sup> This expansion is due in part to a half-century of growth in the creation of new disciplines, scholarly production, and research resource consumption.<sup>31</sup> During that time, researchers and research participants became more mobile

24. Abbott & Grady, *supra* note 22, at 9, 14; Silberman & Kahn, *supra* note 22, at 599, 607. This diversity extends beyond the academy, as a study of Veterans Affairs and VA-Affiliated Medical Center IRBs demonstrated. See Todd H. Wagner, Anne Marie E. Cruz & Gary L. Chadwick, *Economies of Scale in Institutional Review Boards*, 42 MED. CARE 817, 817 (2004).

25. See Schrag, *supra* note 22, at 122–23. But see Tim Bond, *Ethical Imperialism or Ethical Mindfulness? Rethinking Ethical Review for Social Sciences*, 8 RES. ETHICS 97, 104–07 (2012) (response to Schrag) (“The extent to which researchers and ethical reviewers engage in issues around the best methods for seeking adequately informed consent is arguably one of the hallmarks of the degree to which they are seriously committed to being respectful of research participants.”).

26. Robert L. Klitzman, *How IRBs View and Make Decisions About Consent Forms*, 8 J. EMPIRICAL RES. HUM. RES. ETHICS 8, 10 (2013). On how IRB processes, in general, foster legalistic interpretations of regulations by universities, see Caroline H. Bledsoe et al., *Regulating Creativity: Research and Survival in the IRB Iron Cage*, 101 NW. U. L. REV. 593, 609 (2007).

27. See Bond, *supra* note 25, at 104; Mary Faith Marshall et al., *Perinatal Substance Abuse and Human Subjects Research: Are Privacy Protections Adequate?*, 9 MENTAL RETARDATION DEVELOPMENTAL DISABILITIES RES. REV. 54 (2003); John H. Noble, Jr. & Vera Hassner Sharav, *Protecting People with Decisional Impairments and Legal Incapacity Against Biomedical Research Abuse*, 18 J. DISABILITY POL’Y STUD. 230, 241 (2008). On modern, unethical research as a conduit of institutional racism and neocolonialism, see HARRIET A. WASHINGTON, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT* 389 (2008). (“The bad news is that the racial mythology, the medical exploitation of black bodies for profit, and even the instances of medical sadism that threatened African Americans in the past have been exported to Africa.”). On 1990s U.S. government-funded research that denied HIV/AIDS drugs to pregnant women in Uganda, see SUSAN M. REVERBY, *EXAMINING TUSKEGEE: THE INFAMOUS SYPHILIS STUDY AND ITS LEGACY* 228–36 (2009); see also Alexander M. Capron et al., *Pace of Research Should Not Barrel Ahead of Ethical Safeguards*, BOS. GLOBE, Aug. 6, 2015, at A15.

28. JAMES BELL ET AL., NAT’L INSTS. OF HEALTH, FINAL REPORT: EVALUATION OF NIH IMPLEMENTATION OF SECTION 491 OF THE PUBLIC HEALTH SERVICE ACT 49 (June 15, 1998), <https://repository.library.georgetown.edu/handle/10822/914644>; Silberman & Kahn, *supra* note 22, at 607.

29. BELL ET AL., *supra* note 28, at 29; Abbott & Grady, *supra* note 22, at 16.

30. BELL ET AL., *supra* note 28, at 7–10; C.K. Gunsalus et al., *The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB “Mission Creep,”* 13 QUALITATIVE INQUIRY 617, 630–31 (2007); Michael Owen, *Ethical Review of Social and Behavioral Science Research*, in RESEARCH ADMINISTRATION MANAGEMENT 543, 551 (Elliot C. Kulakowski & Lynne U. Chronister eds., 2006).

31. See DIANA CRANE, *INVISIBLE COLLEGES* 171–87 (1972); DEREK J. DE Solla PRICE, *LITTLE SCIENCE, BIG SCIENCE . . . AND BEYOND* 9–10, 62 (1963); Ellickson, *supra* note 1, at 536–38; Posner, *supra* note 1, at 1119.

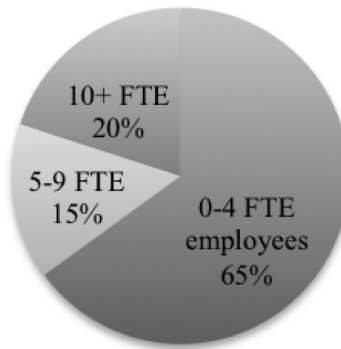


and reliant on new technologies that complicated issues of anonymity, consent, and confidentiality.<sup>32</sup> Simultaneously, the U.S. government provided inconsistent guidance to human research protection programs on “covered research . . . who counts as a research subject” and other key terms.<sup>33</sup> Some IRBs resolved definitional issues by erring on the side of expansive review,<sup>34</sup> while others drew sharp lines that complicated multisite IRB review.<sup>35</sup> Some researchers erred on the side of submitting protocols to their IRBs even when their research did not technically involve human subjects.<sup>36</sup> Even seasoned researchers sometimes clogged IRB pipelines with numerous amendments to hastily designed and IRB-approved protocols.<sup>37</sup>

¶8 Recent data from PRIM&R (Public Responsibility in Medicine and Research), a leading professional organization for IRB staff, demonstrates the workloads of modern IRBs. While more than two-thirds of IRBs employ fewer than five people (see figure 1),<sup>38</sup> most IRBs process hundreds of protocol applications, amendments, and modifications each year (see figures 2 and 3).

**Figure 1**

IRBs Full-Time Staffing Levels (n=497)<sup>39</sup>



32. Patricia L. Price, *Geography, Me, and the IRB: From Roadblock to Resource*, 64 *PROF'L GEOGRAPHER* 34, 37–38 (2012).

33. Gunsalus et al., *supra* note 30, at 626; Lauren B. Solberg, *Data Mining on Facebook: A Free Space for Researchers or an IRB Nightmare?*, 2010 *U. ILL. J.L. TECH. & POL'Y* 311, 316–17.

34. Gunsalus et al., *supra* note 30, at 627–28.

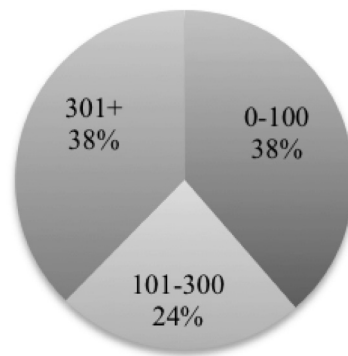
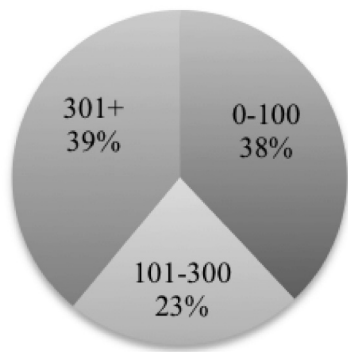
35. Multisite or multicenter review is often required for human subjects research directed by researchers from two or more institutions. See Abbott & Grady, *supra* note 22, at 10–12.

36. For example, when it involved records of deceased individuals. See Solberg, *supra* note 33, at 337–38.

37.Carolynn T. Jones, *Issues in Research Management: Protocol Challenges in the Era of Complexity*, 12 *RES. PRAC.* 121, 121 (2011) (“In addition to the rise in intensity within study protocols, there has been an increase in the number of protocol amendments and revisions in the last decade . . . It is rare for a protocol to be implemented at a [clinical research] site without some sort of study revision.”); Sandra V. Kotsis & Kevin C. Chung, *Institutional Review Boards: What’s Old? What’s New? What Needs to Change?*, 133 *PLASTIC & RECONSTRUCTIVE SURGERY* 439, 441 (2014). For a discussion of related ethical issues, see Lynn A. Jansen, *Local IRBs, Multicenter Trials, and the Ethics of Internal Amendments*, 27 *IRB: ETHICS HUM. RES.* 7, 7–8 (2005).

38. PRIM&R, 2014 IRB WORKLOAD AND SALARY SURVEY [summary statistics PowerPoint] (2014) (on file with author); see also *Grad Assistants Help with One-Person Office*, IRB ADVISOR, July 1, 2014.

39. There were 497 responses to the Number of Full-Time Equivalent Staff 2014 survey item.

**Figure 2**New Applications Submitted to IRBs in 2013 (n=526)<sup>40</sup>**Figure 3**Amendments/Modifications Submitted to IRBs in 2013 (n=440)<sup>41</sup>

¶9 Noting the workloads and challenges of university IRBs, academic law librarians can assist our IRB staff colleagues, faculty, and students by helping to reduce unnecessary submissions and improve the quality of submitted protocols. To do so, we must be conversant in the research designations employed by IRBs. Then, we can help our faculty and students to correctly classify their research, select the proper forms, and execute IRB requirements accurately and completely.

### **Regulatory Classifications: The Four Review Designations IRBs Employ**

¶10 The work of IRBs is best understood in relation to the four research designations suggested by the Public Health Service Act (PHS) and its regulations, which appear in title 45 of the *Code of Federal Regulations*.<sup>42</sup>

40. There were 526 responses to the Number of Initial Reviews of New Studies 2014 survey item. As is discussed below, even exempt protocol applications comprise a number of documents; greater-than-minimal-risk study protocols can be quite lengthy.

41. There were 526 responses to the Number of Amendments or Modifications 2014 survey item.

42. Public Health Service Act, 42 U.S.C. § 289 (2012); Protection of Human Subjects, 45 C.F.R. pt. 46 (2015).

1. Not human subjects research
2. Exempt review permitted
3. Expedited review permitted
4. Full IRB review required

### Not Human Subjects Research

¶11 Not all scholarly work requires IRB review. In a university setting, only those faculty, students, and staff planning to conduct *research with human subjects* must submit IRB protocols prior to commencing work. The phrase “human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.”<sup>43</sup>

¶12 The regulatory definition of human subject excludes historical research about deceased individuals, observations about the behaviors of large crowds acting in public, and some medical specimens.<sup>44</sup>

¶13 Research refers to a “systematic investigation . . . designed to develop or contribute to generalizable knowledge.”<sup>45</sup> Research data can be collected via surveys, interviews, educational tests, and other methodologies. However, if information is collected solely for quality improvement (QI) purposes, such as a library survey of law students’ preferences for print or electronic books, it will not be considered research by most IRBs.<sup>46</sup> Scholars have noted that it can be difficult to draw distinctions between research and “not research” in practice-based data collection efforts.<sup>47</sup> Law school clinics illustrate this dilemma. If a student presents an indigent client with a satisfaction survey, that might be strictly QI and not subject to IRB review. But if the clinic adds questions about the client’s long-term access to legal representation, those questions start to veer into research territory, particularly if the student hopes to generalize across clients and publish the findings. IRB staff can provide guidance on whether an exploration has crossed the research

43. 45 C.F.R. § 46.102(f).

44. See *Frequently Asked Questions from Applicants: Human Subjects Research—Definitions*, NAT’L INSTS. OF HEALTH, [http://grants.nih.gov/grants/policy/hs/faqs\\_aps\\_definitions.htm](http://grants.nih.gov/grants/policy/hs/faqs_aps_definitions.htm) [<https://perma.cc/75VZ-CF86>]; *Not Research or Does Not Involve Human Subjects*, HUMAN RES. PROTECTION OFFICE, UNIV. OF PITTSBURGH, <http://www.irb.pitt.edu/not-research-or-does-not-involve-human-subjects> [<https://perma.cc/GQ7A-LH8A>].

45. 45 C.F.R. § 46.102(d).

46. But see examples of the QI versus research debate in the biomedical sciences: Eran Bellin & Nancy Neveloff Dubler, *The Quality Improvement-Research Divide and the Need for External Oversight*, 91 AM. J. PUB. HEALTH 1512 (2001); David Casarett et al., *Determining When Quality Improvement Initiatives Should Be Considered Research*, 283 J. AM. MED. ASS’N 2275 (2000); Franklin G. Miller & Ezekiel J. Emanuel, *Quality-Improvement Research and Informed Consent*, 358 NEW ENG. J. MED. 765, 767 (2008) (discussing criticized QI research at John Hopkins University that “should have . . . [received] a full or expedited review”).

47. Some seminal IRB guidelines assumed a biomedical research model that is ill suited to the social sciences and law. Gunsalus, *supra* note 30, at 626; see also *Ethical Principles and Guidelines for the Protection of Human Subjects of Research [The Belmont Report]*, HHS.GOV (Apr. 18, 1979), <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> [<https://perma.cc/K65X-4GUU>]. On how some IRB members focus on whether research will produce a scientific product rather than how it is conducted, see Ivor A. Pritchard, *Travelers and Trolls: Practitioner Research and Institutional Review Boards*, 31 EDUC. RESEARCHER 3, 4 (2002).



threshold. If a project involves human subjects research, it will be subject to exempt, expedited, or full IRB review.<sup>48</sup>

### Exempt Review Permitted

¶14 A large swath of human subjects research involves minimal risk to research participants<sup>49</sup> and falls within a federal research exemption category. “*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”<sup>50</sup>

¶15 Section 101 of 45 C.F.R. 46 lists six categories of minimal risk research that “are exempt from this policy,”<sup>51</sup> including most research conducted in classrooms,<sup>52</sup> survey research and interviews,<sup>53</sup> and research involving existing data, if research participants cannot be identified.<sup>54</sup> For some years, the U.S. Department of Health and Human Services (DHHS), which promulgates national IRB regulations, did not require *any* institutional review of exempt research.<sup>55</sup> Officially, *researchers* were free to determine whether their research was exempt.

¶16 Regardless of the loose federal guidelines for exempt research, many universities required researchers to submit truncated exempt protocols to the IRB so that a professional staff member or single IRB member could determine whether the proposed research was exempt.<sup>56</sup> Eventually, the Office for Human Research Protections (OHRP) at the DHHS recommended that “investigators not be given the authority to make an independent determination that human subjects research is exempt.”<sup>57</sup> This updated guidance should signal academic researchers to submit exempt research protocols for review. Unfortunately, some researchers still interpret the word “exempt” literally and perceive no obligation to interact with the IRB.<sup>58</sup> Education of the research community is an important, ongoing activity of the IRB. Law librarians can provide one-on-one, real-time research ethics education on an

48. See, e.g., *Human Research Protection Program*, YALE UNIV., <http://your.yale.edu/research-support/human-research> [<https://perma.cc/39LG-SMT9>]; *Human Research, Getting Started*, YALE UNIV., <http://your.yale.edu/research-support/human-research/submission-process/getting-started> [<https://perma.cc/3MYJ-YVWV>] (“If you are doing research that involves human subjects you will need to obtain IRB approval or an IRB determination of exemption prior to beginning the project.”).

49. See *OPRS Office for the Protection of Research Subjects: Types of IRB Review*, UNIV. S. CAL., <http://oprs.usc.edu/review/typesofirb/> [<https://perma.cc/3ERB-3TR9>] [hereinafter *Types of IRB Review*].

50. 45 C.F.R. § 46.102(i) (2015).

51. *Id.* § 46.101(b).

52. *Id.* § 46.101(b)(1).

53. *Id.* § 46.101(b)(2).

54. *Id.* § 46.101(b)(4).

55. *Exempt Research and Research that May Undergo Expedited Review*, HHS.GOV (May 5, 1995), <http://www.hhs.gov/ohrp/policy/hsc95-02.html> [<https://perma.cc/YH8C-DBS9>].

56. See also F. Richard Ferraro et al., *A Survey Regarding the University of North Dakota Institutional Review Board: Data, Attitudes, and Perceptions*, 133 J. PSYCHOL. INTERDISCIPLINARY APPLIED 272, 277 (1999); Kenneth R. Howe & Michele S. Moses, *Ethics in Educational Research*, 24 REV. RES. EDUC. 21, 48 (1999); *Types of IRB Review*, *supra* note 49.

57. *Exempt Research Determination FAQs*, HHS.GOV, <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/> [<https://perma.cc/XW2T-PEBS>].

58. Interview with Cathleen Montano, IRB Comm. Manager, Yale Univ. (June 25, 2015) (notes on file with author) [hereinafter Interview with Cathleen Montano].

as-needed basis. Specifically, law librarians can assist IRB staff in educating faculty, students, and staff so that exempt protocols are created and submitted; at some institutions, librarians can serve as designated exempt protocol reviewers.<sup>59</sup> Law librarians can also spread the word that exempt review is typically much less time-consuming than expedited or full IRB review.<sup>60</sup>

### Expedited Review Permitted

¶17 If a human research study involves minimal risks<sup>61</sup> to participants but does not fall within one of the federal exemption categories, it might be subject to expedited review.<sup>62</sup> To secure expedited review, the research methodology must align with a category on the DHHS expedited review list of categories.<sup>63</sup> Expeditable research methodologies range from “[c]ollection of blood samples by finger stick, heel stick, ear stick, or venipuncture” to “[c]ollection of data from voice, video, digital, or image recordings made for research purposes.”<sup>64</sup> Expedited protocols may be reviewed by “the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.”<sup>65</sup> Typically, the IRB chair will select faculty reviewers who are familiar with a researcher’s chosen methodology (e.g., ethnography) or routine human subjects protection procedures in the researcher’s field (e.g., cultural anthropology).<sup>66</sup> Selected single reviewers have the authority to approve a protocol, but cannot singularly disapprove of it. So, if they feel that research procedures will not adequately protect participants,<sup>67</sup> the protocol must be routed to the full IRB for review at a future meeting.<sup>68</sup>

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59. This is true at Yale Law School, where I am a designated exempt protocol reviewer. But staff review of exempt protocols would not be required at schools with the most minimal forms of IRB review, as documented by the AAUP. *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, *supra* note 12.

60. For example, a week versus a few weeks or one to two months for exempt, expedited, and full IRB review, respectively. On comparative review times, see Scott Kim et al., *Pruning the Regulatory Tree*, 457 *NATURE* 534, 535 (2009).

61. Note the presence of “or” in the definition of “minimal risk,” *supra* ¶14, which establishes three standards for expedited review. 45 C.F.R. § 46.102(i) (2015); *see also Expedited Review of Social and Behavioral Research Activities*, NAT’L SCI. FOUND. 4–5 (June 2008), <https://www.nsf.gov/pubs/2008/nsf08203/index.jsp> [<https://perma.cc/RRX7-7H82>].

62. For cross-national understandings of “minimal risk” in the context of expedited review, see Loretta M. Kopelman, *Minimal Risk as an International Ethical Standard in Research*, 29 *J. MED. PHIL.* 351, 356–57 (2004).

63. 45 C.F.R. § 46.110 (“The Secretary, HHS, has established, and published as a Notice in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure.”); *see also* Protection of Human Subjects: Categories of Research that May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure [Notice], 63 *Fed. Reg.* 60364 (Nov. 9, 1998).

64. Protection of Human Subjects, 63 *Fed. Reg.* at 60365–66.

65. 45 C.F.R. § 46.110(b)(2).

66. Elizabeth Smith Parrott, *Ethnographic Research*, in *INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION* 402, 406 (Elizabeth A. Bankert & Robert J. Amdur eds., 2006).

67. 45 C.F.R. § 46.110(b)(2).

68. Gwenn S.F. Oki & John A. Zaia, *Expedited Institutional Review Board Review*, in *INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION*, *supra* note 66, at 97.

¶18 Expedited reviewers—and full IRBs—review each proposal separately according to seven criteria specified in the federal regulations:

- (1) Risks to subjects are minimized . . . .
- (2) Risks to subjects are reasonable in relation to anticipated benefits . . . .
- (3) Selection of subjects is equitable . . . .
- (4) Informed consent will be sought from each prospective subject . . . .
- (5) Informed consent will be appropriately documented . . . .
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<sup>69</sup>

Reviewers pay particular attention to studies involving vulnerable populations, “such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.”<sup>70</sup>

### Full IRB Review Required

¶19 An IRB meeting comes to order when a “majority of the members of the IRB are present”;<sup>71</sup> typically, this will be seven or more faculty members.<sup>72</sup> IRB staff members also attend and provide regulatory guidance, record meeting minutes,<sup>73</sup> and collect follow-up questions and directions for researchers,<sup>74</sup> who are often referred to as principal investigators, or PIs, throughout the meeting.

¶20 At the start of each protocol discussion, a single IRB member might recite basic study information gleaned from the IRB application. Then, various board members will discuss human subjects protections issues they noticed when reading the entire submission packet, including recruitment tools (e.g., flyers), consent forms, interviewer training documents, and so on.<sup>75</sup> If the research involves a “vulnerable population” such as prisoners,<sup>76</sup> IRB members will critically examine

69. See 45 C.F.R. § 46.111(a). Note, there is some flexibility in the process. The regulations do not specify, for instance, that the seven criteria must be considered in the order listed above.

70. *Id.* § 46.111(b).

71. *Id.* § 46.108(b).

72. On average (i.e., mean) IRB sizes and compositions, see Raymond de Vries & Carl P. Forsberg, *Who Decides? A Look at Ethics Committee Membership*, 14 HEC FORUM 252, 253–54 (2002). De Vries and Forsberg found that the most common professional affiliation of an IRB member was physician. *Id.* at 254. This finding would not hold for social science–dedicated IRBs. Some institutions (e.g., Yale) bifurcate IRB work into biomedical and social science IRBs.

73. Meeting minutes are vital, as they are used in audits of IRBs and can demonstrate whether an IRB has met the burdens set out in the relevant regulations. *Best Practices: Improving Meeting Minutes Documentation*, IRB ADVISOR, Jan. 1, 2013.

74. Some examples of these are: “Please send us your revised consent form when it is completed,” and “Tell us more about how you will recruit participants in the rural areas.” Questions such as these were observed when I attended a full IRB meeting at Yale University on July 9, 2015. Sometimes protocols are approved even if the IRB requests additional documentation; sometimes protocol review is tabled until a researcher completes, corrects, or supplements a submitted protocol. See BELL ET AL., *supra* note 28, at 29; Abbott & Grady, *supra* note 22, at 16.

75. I observed this process when I attended a full IRB meeting at Yale University on July 9, 2015. For a rich collection of sample documents, see *IRB Applications, Forms and Samples*, BOISE STATE UNIV., <http://research.boisestate.edu/compliance/institutional-review-board-irb-home/irb-applications-forms-and-samples/> [<https://perma.cc/7JJM-Q3L6>].

76. 45 C.F.R. § 46.111(b).

“whether risks are minimized adequately” and make determinations about the protocol as required by the regulations. IRB staff will likely record explicit details of the discussion in the meeting minutes.<sup>77</sup> Overall, the goal of the IRB is to promote ethical treatment of research subjects and sufficient screening to reduce the risk of a “federal for-cause audit” while also respecting diverse research methods and topics of study.<sup>78</sup> Law librarians could assist IRBs by performing research and regulatory work across research review types.

¶21 Table 1 summarizes the four research designations discussed in this section.

**Table 1**

**Types of Human Subjects Research Review, Reviewers, and Regulations**

<b>Review Type</b>	<b>Research Type</b>	<b>Who Can Review?</b>	<b>Key Regulations</b>
Exempt	Minimal risk and meets one of six exemption categories	Trained professional staff member, including law librarian or single IRB member	45 C.F.R. § 46.101
Expedited	Minimal risk and aligns with one or more expedited review research categories	IRB chair or IRB member(s) designated by chair	45 C.F.R. § 46.110 63 Fed. Reg. 60364
Full IRB	Not minimal risk or does not meet either exempt or expedited review categories	Full IRB	45 C.F.R. § 46.111

**Performing Research and Regulatory Work**

¶22 Law librarians could perform research and regulatory work aimed at improving the quality of IRB submissions, increasing the efficiency of IRB review, and enhancing the empirical research practice literacy of law school faculty, students, and staff. In current practice, initial protocol screening is performed by IRB staff,<sup>79</sup> who also field calls from researchers,<sup>80</sup> and train faculty, students, and staff.<sup>81</sup> Most IRB staff have bachelors or masters degrees; some hold J.D. or doctoral degrees (see figure 4).<sup>82</sup>

77. *Risk-Benefit Assessment: One Size Doesn't Fit All*, IRB ADVISOR, Sept. 1, 2013; Interview with Cathleen Montano, *supra* note 58.

78. Price, *supra* note 32, at 40.

79. *IRB Workload Sharing Strategy Reduces Board Member Fatigue*, IRB ADVISOR, Nov. 1, 2014; see also Abbott & Grady, *supra* note 22, at 10–12; Solberg, *supra* note 33, at 337–38.

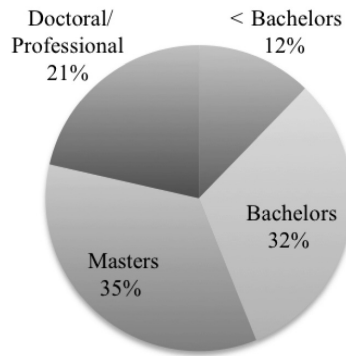
80. Jan Blustein et al., *Notes from the Field: Jumpstarting the IRB Approval Process in Multicenter Studies*, 42 HEALTH SERV. RES. 1773, 1778 (2007).

81. *Institution Provides IRB Members with Thorough, Ongoing Training/Education*, IRB ADVISOR, Feb. 1, 2008; *OHRP Letter Highlights Importance of Having Student Subject P&Ps*, IRB ADVISOR, Mar. 17, 2015; Danielle Whicher, *The Views of Quality Improvement Professionals and Comparative Effectiveness Researchers on Ethics, IRBs, and Oversight*, J. EMPIRICAL RES. HUM. RES. ETHICS 7 (2015) (online release of article).

82. PRIM&R, *supra* note 38; see also *Success with IRB Staffing Begins with Interview Process*, IRB ADVISOR, Nov. 1, 2014 (“While 30 years ago an IRB could rely on a long-time employee who had

**Figure 4**

Degrees Held by PRIM&amp;R 2014 Survey Respondents (n=472)



¶23 Like their IRB colleagues, law librarians handle informational telephone calls and e-mails, review drafts of research proposals, organize and catalog learning resources, and provide training on a host of research topics and methodologies.<sup>83</sup> And law librarians tend to hold graduate degrees. Nearly all law library jobs require a masters in information or library science and “[a]bout one-third of all law librarians also have a law degree.”<sup>84</sup> Additionally, our professional proficiency requires continual (re)training in new information systems, resource classification schema, and research techniques.<sup>85</sup> Adding human subjects research services to academic law library portfolios would require training akin to what technical services librarians have completed to learn RDA (Resource Description and Access)<sup>86</sup> or myriad law librarians have undertaken to hone their empirical legal research skills.<sup>87</sup> Human subjects research services would align to the four designations employed by IRBs.

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experience without credentials, this model is becoming rare. These days, IRBs increasingly are staffed with people who have bachelor’s and master’s degrees and human research subjects protection certification.”).

83. Butler, *supra* note 1, at 240; Lewis, *supra* note 2, at 90; see also Farhad Daneshgar & Mehri Parirokh, *An Integrated Customer Knowledge Management Framework for Academic Libraries*, 82 LIBR. Q. 7, 16 (2012).

84. Alyssa Thurston, *Addressing the “Emerging Majority”: Racial and Ethnic Diversity in Law Librarianship in the Twenty-First Century*, 104 LAW LIBR. J. 359, 368, 2012 LAW LIBR. J. 27, ¶ 26; *Education Requirements*, AM. ASS’N OF LAW LIBRARIES, <http://www.aallnet.org/mm/Careers/lawlibrarycareers/Education-Requirements> [<https://perma.cc/N6EJ-BXYQ>]. See also Elizabeth Caulfield, *Is This a Profession? Establishing Educational Criteria for Law Librarians*, 106 LAW LIBR. J. 287, 322, 2014 LAW LIBR. J. 19, ¶ 119.

85. Robert C. Berring, *The Education of a Twentieth-Century Law Librarian*, 32 LEGAL REFERENCE SERVS. Q. 1, 11 (2013); Ann Chapman, *The Case of AACR2 Versus RDA*, 10 LEGAL INFO. MGMT. 210 (2010); Ryan & Miguel-Stearns, *supra* note 13, at 9, 11; Jordon Steele & Ed Greenlee, *Thinking, Writing, Sharing, Blogging: Lessons Learned from Implementing a Law Library Blog*, 103 LAW LIBR. J. 113, 120, 2011 LAW LIBR. J. 6, ¶ 31; Hollie White et al., *Digitizing and Preserving Law School Recordings: A Duke Law Case Study*, 21 NEW REV. ACAD. LIBR. 232 (2015).

86. See Chapman, *supra* note 85, at 211–12.

87. Stephanie Ball, *Managing Big Data: What’s Relevant?*, AALL SPECTRUM, Nov. 2013, at 25; Ellen Qualey, *What Can Infographics Do for You?*, AALL SPECTRUM, Feb. 2014, at 7; Ryan, *supra* note 14.

### Not Human Subjects Research Library Work

¶24 Every IRB protocol review starts with a single question: Is this human subjects research? As previously discussed, both “human subjects” and “research” are defined in the regulations that govern IRB work. Still, applying these definitions to a specific research project requires information about local interpretations of federal regulations and judgment. For instance, each IRB is likely to have a slightly different bright line for what constitutes QI versus human subjects research.<sup>88</sup> Given the rise of QI initiatives at health centers and among academic researchers, some IRBs have created educational materials and forms to facilitate researcher understanding and streamline requests for “not human subjects research” determinations.<sup>89</sup> Law librarians can assist researchers in finding such documents and determining how to classify their work. In some instances, law librarians can render initial determinations of “not human subjects research” for their university IRBs.<sup>90</sup>

¶25 Some typical law faculty, student, and staff projects illustrate how such determinations might work. For instance, if a faculty member talked “on background” to attorneys at the Environmental Protection Agency to determine whether citizen lawsuits against the agency were increasing or decreasing, this would likely *not* be human subjects research. A law librarian could ask clarifying questions of the faculty member such as, “Do you plan to publish quotes from your discussions with these attorneys?” or “Are you going to aggregate their responses and publish those statistics?” A “yes” answer to either question would suggest that the faculty member might be conducting human subjects research. But the research might still be “not human subjects research” if all of the interview questions concerned *agency* trends rather than individual attorneys’ beliefs, experiences, or legal strategies.

¶26 Similarly, a student might interview members of the local bar association about their workloads, work-life balance, and career satisfaction. If the interviews were conducted as part of the student’s job-hunting process, they would not constitute human subjects research. But if the student hoped to publish an article in the local bar journal, the project would veer into human subjects research terrain. Comparably, if staff of a law school’s career development office (CDO) wanted to survey alumni about their ongoing professional development needs, that project would typically complement the office’s ongoing QI work. However, if the CDOs of five law schools surveyed their students and hoped to publish a cross-institutional analysis in an academic journal, that would signal human subjects research.

¶27 Law librarians could push patrons to consider their “best-case scenario” research goals (e.g., publication) to determine how likely they would be to cross the threshold of human subjects research.<sup>91</sup> If a project were likely to cross that line, law librarians could help researchers determine whether to submit an exempt review application or an expedited/full IRB review application. Law librarians

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88. See Bellin & Dubler, *supra* note 46; Casarett et al., *supra* note 46; Miller & Emanuel, *supra* note 46.

89. See *Human Research Protection Program*, *supra* note 48; *IRB Develops Non-Research QI Templates*, IRB ADVISOR, Apr. 1, 2014.

90. As previously noted, reviews that occur lower on the IRB pyramid, such as determining that work is not human subjects research, may be completed entirely by professional staff, including librarians. See *Human Research Protection Program*, *supra* note 48.

91. Retroactive approval of research that has crossed the human subjects research threshold is not possible. See *Institutional Review Board*, *supra* note 12.



could also assist researchers in understanding and completing required presubmission work, such as research ethics training.<sup>92</sup>

### Exempt Review Library Work

¶28 Human subjects research that falls under one of the regulatory exemption categories still requires staff member review at nearly all U.S. universities.<sup>93</sup> If the staff reviewer agrees that the research is exempt, the IRB will issue the researcher an exemption letter.<sup>94</sup> This letter can be cited in research article footnotes.

¶29 Minimally, law librarians can assist faculty, students, and staff in assembling accurate and complete exempt protocols. At Yale, a Social, Behavioral, and Educational Research exempt protocol contains six components:

1. Conflict of interest form, submitted through the university portal
2. Human subjects research training (online certification)
3. Request for HSC Determination of Exempt Status form
4. Survey, interview, focus group, etc., script, if using a script
5. Consent form or script for verbal or written consent<sup>95</sup>
6. Recruitment document, if using a written recruitment instrument, or script for verbal recruitment (if applicable)<sup>96</sup>

¶30 Like Yale, most universities require each member of the research team to complete human subjects research training.<sup>97</sup> Many institutions use a customizable training course created by the Collaborative Institutional Training Initiative (CITI).<sup>98</sup> Researchers must repeat this training regularly (e.g., every three years), so faculty with previously accepted protocols might need to train again. In addition to assisting researchers in assembling their protocols, “deputized” law librarians can serve as staff screeners of exempt protocols.

¶31 Exempt protocol screenings revolve around a series of questions implicated by the regulatory exemption categories.<sup>99</sup> A typical initial question, “Will you use existing data?” is particularly relevant for law school constituents, who often mine government datasets. If legal data is reported at the institutional level, such as the number of prisoners housed in each U.S. prison, it will be classified as “not human

92. For a timeline of typical presubmission work, see Sarah E. Ryan, *The Rhyme and Reason of IRBs: Navigating the Human Subjects Research Review Process*, AALL SPECTRUM, Feb. 2014, at 30.

93. Ferraro et al., *supra* note 56, at 277; Howe & Moses, *supra* note 56, at 48; *Exempt Research Determination FAQs*, *supra* note 57.

94. See *Exempt Research Studies Involving Human Subjects*, JOHN HOPKINS MED. (Apr. 2016), [http://www.hopkinsmedicine.org/institutional\\_review\\_board/guidelines\\_policies/guidelines/exempt\\_research.html](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/exempt_research.html) [<https://perma.cc/575X-2AFR>]; *Human Research Protection Program*, *supra* note 48.

95. Some surveys will include the consent language in a survey box/block/slide. In that instance, the consent language will be contained in item #4: survey instrument.

96. Sarah E. Ryan, *Human Subjects Research Review at YLS: Exempt Review Quick Process and IRB Assistance* (2015) (on file with author). An e-mail would be considered a written recruitment instrument by many IRBs.

97. Emily E. Anderson, *Research Ethics Education for Community-Engaged Research: A Review and Research Agenda*, 7 J. EMPIRICAL RES. HUM. RES. ETHICS 3, 8 (2012); *Find the Right CBPR Training for Your IRB*, IRB ADVISOR, Jan. 1, 2015; *Required Ethics Training*, UNC RES., <http://research.unc.edu/offices/human-research-ethics/getting-started/training/> [<https://perma.cc/V277-LPWK>].

98. *Find the Right CBPR Training for Your IRB*, *supra* note 97; *Online Courses*, CITI PROGRAM, <http://www.citiprogram.org/index.cfm?pageID=86> [<https://perma.cc/5ETG-YMGA>].

99. 45 C.F.R. § 46.101(b) (2015).

subjects research.”<sup>100</sup> And much human subjects justice data is anonymized before it is released publicly,<sup>101</sup> so it will often qualify for exempt review.<sup>102</sup> A reviewer employing an exempt review decision tree would likely determine that unidentifiable individual data merits a category 4 exemption (see figure 5).

¶32 If a human subjects protocol does not meet one of the exemption categories, law librarians can assist faculty members in preparing an expedited/full IRB review protocol submission.

### Expedited/Full IRB Review Library Work

¶33 Both expedited and full IRB reviews must be handled by IRB members. Expedited reviews sometimes proceed more quickly because IRB chairs can designate the work to just one or two board members.<sup>103</sup> But in either case, protocol approval takes significantly longer than exemption determinations. Additionally, completed expedited/full IRB review protocols are usually much longer than exempt review protocols.<sup>104</sup> Some university IRBs maintain separate application forms for expedited and full IRB review,<sup>105</sup> but many combine the two review types in a single application form.<sup>106</sup>

¶34 As with exempt protocols, law librarians can assist researchers in assembling high-quality expedited/full IRB protocol submissions, including human research training certificates. At most law schools, this will be a low-volume service (e.g., fewer than a dozen per year).<sup>107</sup> Beyond that work, law librarians can facilitate efficient, high-quality review by teaching patrons about the intent behind IRB review and by collecting human subjects research protection resources.

100. See, e.g., *Census of State and Federal Adult Correctional Facilities, 2005 (ICPSR 24642)*, ICPSR, <http://www.icpsr.umich.edu/icpsrweb/ICPSR/studies/24642> [<https://perma.cc/7LCD-HCBT>].

101. See, e.g., U.S. DEP'T HEALTH & HUMAN SERVS., NATIONAL INTIMATE PARTNER AND SEXUAL VIOLENCE SURVEY: GENERAL POPULATION SURVEY RAW DATA, 2010 (2014) (“To protect respondent privacy, all perpetrator names and/or initials have been anonymized as [PERP 01] . . .”).

102. Important exceptions exist, such as federally funded, preexisting, anonymized prisoner data; it typically cannot be exempt. Cathleen Montano and other members of the Yale HRPP have educated me about such issues. Readers are encouraged to ask local IRB staff about vulnerable population research, as such research reveals the nuances of the federal regulations.

103. See 45 C.F.R. § 46.110(b)(2). But see Kim et al., *supra* note 60, at 535, on how expedited and full board review times are identical for some protocols at some institutions.

104. I reviewed exempt protocol examples submitted at Yale, and they tended to be two or three pages long. By contrast, an expedited/full board protocol can run a dozen or more pages. I could not find solid guidance on the typical page lengths of exempt versus expedited/full IRB applications. I did find examples of remarkably long appendixes, such as twenty-seven-page (i.e., median length for the institution) consent forms. See *True Simplicity Remains Elusive for IC Forms*, IRB ADVISOR, Feb. 1, 2013.

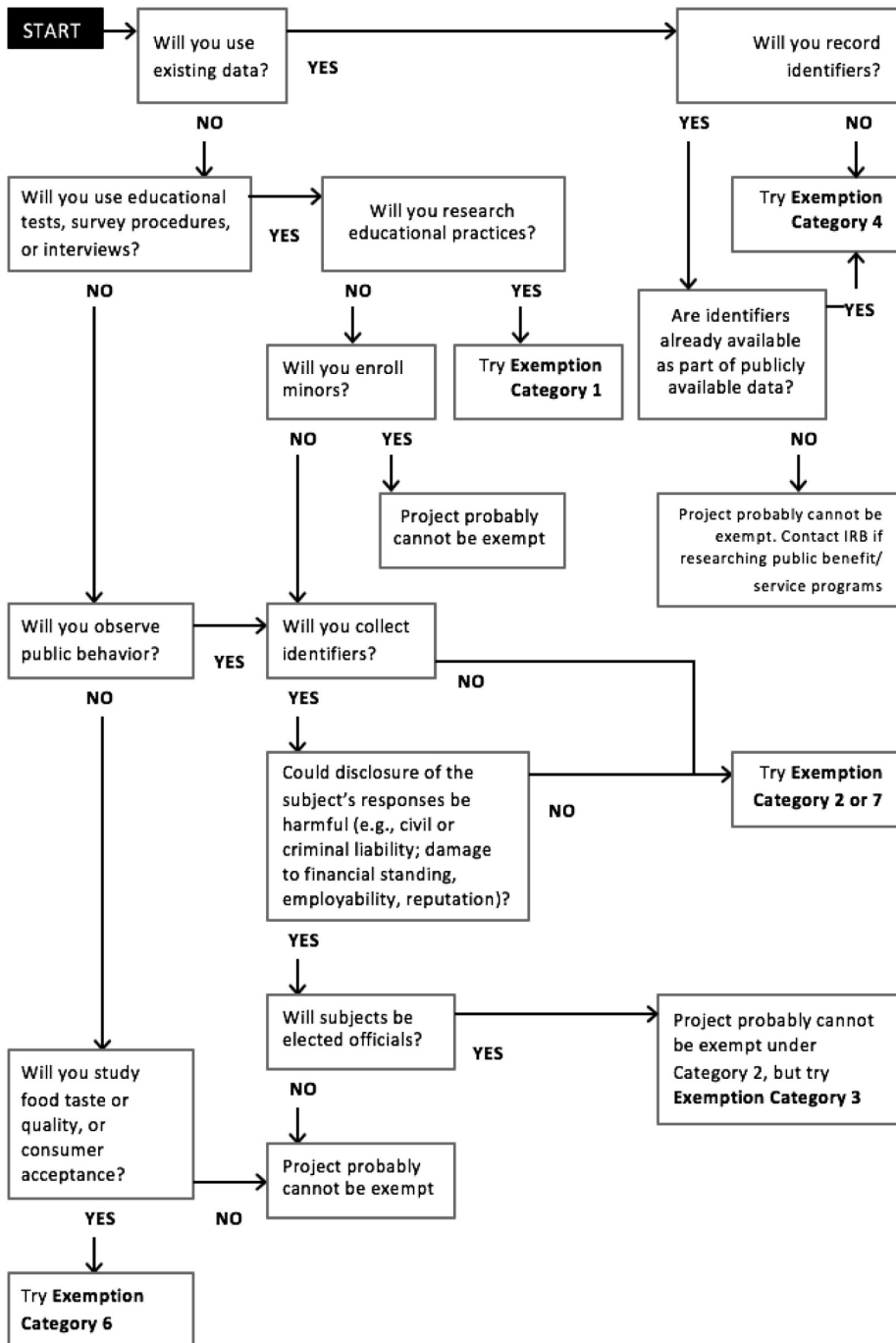
105. See *IRB Review Types*, UNIV. OF KY. OFFICE OF RES. INTEGRITY, <http://www.research.uky.edu/ori/human/IRBReviewTypes.htm> [<https://perma.cc/Z9ZK-JG9E>].

106. See *Human Research Protection Program, Forms & Templates: Social, Behavioral & Educational Research: Application Form*, YALE UNIV., <http://your.yale.edu/research-support/human-research/forms-templates> [<https://perma.cc/3Z6F-VCY4>].

107. I am generalizing from Yale, where the IRB typically receives fewer than a dozen IRB submissions from the law school each year. It is worth noting that Yale Law School has a relatively large cohort of law and social science faculty.

Figure 5

Sample Exempt Protocol Decision Tree<sup>108</sup>



108. Created by Yale Human Research Protection Program and adapted by Ryan, *supra* note 96. Yale has a seventh category of exemption that most institutions will not have.

¶35 First, law librarians can educate patrons, particularly students, about the focus and intent of IRB reviewers. In my experience, student researchers tend to concentrate too heavily on their desired outcomes and too lightly on their research processes in IRB applications.<sup>109</sup> That is, they focus on persuading reviewers that their projects are intellectually meritorious rather than reasonably safe. While the “anticipated benefits” of research matter to IRB members—and to drafters of federal regulations governing human subjects protections<sup>110</sup>—the management and minimization of risks to research participants is the focus of protocol review.<sup>111</sup> Federal regulations repeatedly instruct IRB members to consider risks, consent, safety, and privacy.<sup>112</sup> Law librarians can educate patrons about such considerations, including research data confidentiality. For instance, we can provide workshops on the pitfalls of cloud storage,<sup>113</sup> write blog posts about health data regulations,<sup>114</sup> and showcase data protection technologies during library orientations.<sup>115</sup> To complement new educational offerings, we can collect resources on research risks and best practices in human subjects protections.

¶36 Second, law librarians can foster ethical study design by collecting human subjects research protection resources. These can include books about the history of research abuses and the rise of formal review,<sup>116</sup> how modern IRBs operate,<sup>117</sup> or how IRBs intersect with legal practice, particularly in health law.<sup>118</sup> Additionally, law librarians can build bibliographies of published articles that divulge successful

109. I have reviewed about a dozen new protocols at Yale Law School, some of which were not ultimately submitted to the Yale IRB. During previous work at other universities, I noticed a similar trend across a number of communication and public affairs graduate student protocols.

110. 45 C.F.R. § 46.111(a)(2) (2015).

111. Evaluation of risk is fraught. See SOC. & BEHAVIORAL SCIS. WORKING GROUP ON HUMAN RES. PROTECTIONS, AM. EDUC. RES. ASS'N, RISK AND HARM (Jan. 2004), [http://www.aera.net/Portals/38/docs/About\\_AERA/humansubjects\\_risk\\_harm.pdf](http://www.aera.net/Portals/38/docs/About_AERA/humansubjects_risk_harm.pdf) [<https://perma.cc/776C-BYSM>].

112. 45 C.F.R. § 46.111. While the regulations are not crystal clear on the distinction between privacy and confidentiality, members of our HRPP have indicated that privacy refers to the person whereas confidentiality refers to the data. Of course, context influences such distinctions.

113. Nancy J. King & V.T. Raja, *What Do They Really Know About Me in the Cloud? A Comparative Law Perspective on Protecting Privacy and Security of Sensitive Data*, 50 AM. BUS. L.J. 413, 414 (2013). (“Although consumers and companies may find economic and other advantages in adopting cloud computing for their information processing needs, they must also consider the risks of cloud computing for sensitive personal data.”).

114. Katherine J. Strandburg, *Monitoring, Datafication, and Consent: Legal Approaches to Privacy in the Big Data Context*, in PRIVACY, BIG DATA, AND THE PUBLIC GOOD 5, 28 (Julia Lane et al. eds., 2014).

115. For example, encrypted USBs. See Donna L. O'Malley, *Gaining Traction in Research Data Management Support: A Case Study*, 3 J. ESCI. LIBR. 74, 75 (2014); Carol Tenopir et al., *Research Data Management Services in Academic Research Libraries and Perceptions of Librarians*, 36 LIBR. INFO. SCI. RES. 84 (2014). Similarly, once trained, we could teach patrons about the computer-automated systems that many IRBs employ or are adopting. On automated systems and IRB efficiency, see Karl Oder & Stephanie Pittman, *The Effect of Computer Automation on Institutional Review Board (IRB) Office Efficiency*, 20 RES. MGMT. REV. 1 (2015).

116. E.g., REVERBY, *supra* note 27; LAURA STARK, BEHIND CLOSED DOORS: IRBs AND THE MAKING OF ETHICAL RESEARCH (2012); WASHINGTON, *supra* note 27.

117. E.g., ROBERT AMDUR & ELIZABETH A. BANKERT, INSTITUTIONAL REVIEW BOARD: MEMBER HANDBOOK (3d ed. 2011); INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION (Elizabeth A. Bankert & Robert J. Amdur eds., 2006); STARK, *supra* note 116.

118. E.g., BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 1743 (2013). On informed consent more generally, see JANET L. DOLGIN & LOIS L. SHEPHERD, BIOETHICS AND THE LAW 46 (3d ed. 2013).

human subjects protection measures.<sup>119</sup> Legal researchers can consult the methodology sections and appendices of these articles for examples of research recruitment procedures, survey or interview scripts, informed consent texts, and so on. Teaching and collection efforts can round out the new service area, which will enhance existing reference, faculty service, and library outreach offerings.

## Conclusion

¶37 Human subjects research assistance makes sense as an academic law library service because it complements existing reference work, faculty services, and library outreach efforts. Reference librarians routinely assist researchers in finding studies related to their topics; human subjects research reference shifts this focus to the methods sections and appendices of published works. Faculty services librarians already track down documents for faculty research projects; IRB services add new forms and templates to the cacophony of resources obtained by faculty services librarians. Library outreach currently connects academic law librarians to their research communities in an effort to assess emerging needs; human research assistance addresses a need voiced by diverse faculty and students, including law school constituents. This new type of outreach signals a commitment to weathering challenging times via innovation.

¶38 Like many law schools, law libraries are facing stagnant or declining budgets.<sup>120</sup> In the wake of financial challenges and changes in legal education, academic law libraries are developing services consonant with emerging legal practice, research, and teaching areas.<sup>121</sup> Though empirical research services still occupy a small segment of most law library portfolios, they can be among the most appreciated offerings,<sup>122</sup> partly because they respond to unmet needs. Human subjects research support not only acknowledges faculty frustrations with university inefficiencies,<sup>123</sup> but it also indicates that librarians understand the flow of faculty research work.<sup>124</sup> Further, human subjects reference work can bolster empirical

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119. For an article that describes rationales for and best practices in web-based research, health research, and research involving minors, and that discusses recruitment, informed consent and debriefing, privacy and confidentiality, and participant safety, see Ellen M. Henderson et al., *Case Study: Ethical Guidance for Pediatric e-Health Research Using Examples from Pain Research with Adolescents*, 37 J. PEDIATRIC PSYCHOL. 1116 (2012). For a description of participant inclusion criteria, consent processes involving a team of researchers, and questionnaire development in a paper-based survey, see F. Hacard et al., *Patients' Acceptance of Medical Photography in a French Adult and Paediatric Dermatology Department: A Questionnaire Survey*, 169 BRIT. J. DERMATOLOGY 298 (2013). For copies of the researchers' adults and minors survey instruments, see the Supporting Information tab on the publisher's website: <http://onlinelibrary.wiley.com/doi/10.1111/bjd.12345/supinfo>.

120. Taylor Fitchett, James Hambleton, Penny Hazelton, Anne Klinefelter & Judith Wright, *Law Library Budgets in Hard Times*, 103 LAW LIBR. J. 91, 2011 LAW LIBR. J. 5.

121. Kenneth J. Hirsh, *Like Mark Twain: The Death of Academic Law Libraries Is an Exaggeration*, 106 LAW LIBR. J. 521, 527, 2014 LAW LIBR. J. 29, ¶ 20.

122. On how data services are sometimes more perceived and appreciated than other information services, see Glon, *supra* note 13, at 17; Simon Lord, *Closing the Gap: The Five Essential Attributes of the Modern Information Professional*, 14 LEGAL INFO. MGMT. 258, 262 (2014).

123. *Supra* ¶ 6 and notes 22–29.

124. Richard A. Danner, *Supporting Scholarship: Thoughts on the Role of the Academic Law Librarian*, 39 J. LEGAL EDUC. 365, 378 (2010); see also Wade R. Kotter, *Bridging the Great Divide: Improving Relations Between Librarians and Classroom Faculty*, 25 J. ACAD. LIBR. 294, 301 (1999).

research grant applications,<sup>125</sup> demonstrating library recognition of the increasing emphasis on faculty revenue generation.<sup>126</sup> Similarly, IRB support can enhance the quality of service to an institution of great importance to law students (and faculty): law reviews.<sup>127</sup>

¶39 It is worth noting that sweeping changes have been proposed to the federal regulations governing IRB work.<sup>128</sup> For instance, one of the largest alterations to the regulatory framework, or “Common Rule,” would allow PIs to self-determine that certain projects were exempt and self-report that determination to their IRBs.<sup>129</sup> Such a system would likely increase the need for researcher education, decrease IRB review work, and increase randomized compliance check-ins with the PIs of exempt research.<sup>130</sup> Law librarians should take away two points from the current discussion of proposed changes to the Common Rule: (1) education and protocol review support would still be needed under the new regime, and (2) widespread changes to human subjects research rules will take years to implement.<sup>131</sup> Additionally, there might be an opportunity for law librarians to help students and faculty transition to new federal and campus practices.

¶40 More generally, a conversation about adding human subjects research services to an academic law library portfolio can spark information gathering and problem solving around a number of important questions, such as:

1. What is slowing down our patrons’ research?
2. What university research and teaching processes could the law library assist with, circumvent, speed up, disseminate information about, and so on?
3. What institutional work meshes with our existing skill sets in data discovery, resource acquisition, patron training, and administrative law?
4. What research and teaching support work meshes with our training in information science (e.g., research data management)?

¶41 These questions intimate the broader purpose behind this article: to contribute to the lively debate about the constitution of twenty-first-century academic law library services. The legal profession and law schools are changing, and so are law libraries. While no academic law library has the resources to offer every conceivable service, the addition of highly visible, low-volume, interesting, and value-added offerings like human subjects research support illustrate the sorts of exciting new initiatives we might explore in the coming years.

125. E.g., *Law & Social Sciences (LSS)*, *supra* note 20.

126. James G. Milles, *Legal Education in Crisis, and Why Law Libraries Are Doomed*, 106 *LAW LIBR. J.* 507, 519, 2014 *LAW LIBR. J.* 28, ¶ 40.

127. See Benjamin J. Keele & Michelle Pearse, *How Librarians Can Help Improve Law Journal Publishing*, 104 *LAW LIBR. J.* 383, 395, 2012 *LAW LIBR. J.* 28, ¶ 38.

128. Department of Homeland Security et al., 80 Fed. Reg. 53933 (proposed Sept. 8, 2015) (extension of comment period until Jan. 6, 2016).

129. This could be done using checklists or web-based tools. See Kathy L. Hudson & Francis S. Collins, *Bringing the Common Rule into the 21st Century*, 373 *NEW ENG. J. MED.* 2293, 2295 (2015).

130. Ivor A. Pritchard, *Regulating Behavioral Research Behavior: Back to the Future?*, Keynote Speech at the 2015 Social, Behavioral, and Educational Research (SBER) Conference of Public Responsibility in Medicine and Research (PRIM&R) (2015) (notes on file with author).

131. *Id.*