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## Beyond IRBs: Ethical Guidelines for Data Research

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# Beyond IRBs: Ethical Guidelines for Data Research

Omer Tene and Jules Polonetsky\*

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## *I. Introduction*

The ethical framework applying to human subject research in the biomedical and behavioral research fields dates back to the Belmont Report.<sup>1</sup> Drafted in 1979 and adopted by the U.S.

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1. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS RESEARCH (1979), <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> (last visited Apr. 19, 2016) (on file with the Washington and Lee Law Review).

government in 1991 as the Common Rule,<sup>2</sup> the Belmont principles were geared towards a paradigmatic controlled, scientific experiment, with a limited population of human subjects interacting directly with researchers and manifesting their informed consent. These days, researchers in academic institutions, as well as private sector businesses not subject to the Common Rule, conduct analysis of a wide array of data sources, from massive commercial or government databases to individual tweets or Facebook postings publicly available online, with little or no opportunity to directly engage human subjects to obtain their consent or even inform them of research activities. The challenge of fitting the round peg of data-focused research into the square hole of existing ethical and legal frameworks will determine whether society can reap the tremendous opportunities hidden in the data exhaust of governments and cities, health care institutions and schools, social networks and search engines, while at the same time protecting privacy, fairness, equality, and the integrity of the scientific process. One commentator called this “the biggest civil rights issue of our time.”<sup>3</sup>

These difficulties afflict the application of the Belmont Principles to even the academic research that is directly governed by the Common Rule. In many cases, the scoping definitions of the Common Rule are strained by new data-focused research paradigms. For starters, it is not clear whether research of large datasets collected from public or semi-public sources even constitutes human subject research. “Human subject” is defined in the Common Rule as “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>4</sup> Yet, data driven research often

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2. U.S. DEPT OF HEALTH & HUMAN SERVS., FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS, <http://www.hhs.gov/ohrp/humansubjects/commonrule/> (last visited Apr. 19, 2016) [hereinafter COMMON RULE] (on file with the Washington and Lee Law Review).

3. Alistair Croll, *Big Data Is Our Generation's Civil Rights Issue, and We Don't Know It*, O'REILLY RADAR (Aug. 2, 2012), <http://radar.oreilly.com/2012/08/big-data-is-our-generations-civil-rights-issue-and-we-dont-know-it.html> (last visited Apr. 19, 2016) (on file with the Washington and Lee Law Review).

4. 45 C.F.R. § 46.102(f) (2015).

leaves little or no footprint on individual subjects (“intervention or interaction”), such as in the case of automated testing for security flaws.<sup>5</sup> As Michael Zimmer notes in his paper for this symposium, “[T]he perception of a human subject becomes diluted through increased technological mediation.”<sup>6</sup> Arvind Narayanan and Bendet Zevenbergen explain that “the Internet is more properly understood as a sociotechnical system in which humans and technology interact.”<sup>7</sup> Moreover, the existence—or inexistence—of identifiable private information in a dataset has become a source of great contention, with de-identification “hawks” lamenting the demise of effective anonymization<sup>8</sup> even as de-identification “doves” herald it as effective risk mitigation.<sup>9</sup>

Along with the definitional contours of the Common Rule, the Belmont principles themselves also require reexamination. The first principle, *respect for persons*, is focused on individual autonomy and its derivative application, informed consent. While obtaining individuals’ informed consent may be feasible in a controlled research setting involving a well-defined group of individuals, such as a clinical trial, it is untenable for researchers experimenting on a

5. See, e.g., Arvind Narayanan & Bendert Zevenbergen, *No Encore for Encore? Ethical Questions for Web-Based Censorship Measurement* (Sept. 24, 2015), <http://ssrn.com/abstract=2665148> (last visited Apr. 19, 2016) (describing ethical issues related to the Encore project) (on file with the Washington and Lee Law Review).

6. Michael Zimmer, *Research Ethics in the Big Data Era: Addressing Conceptual Gaps for Researchers and IRBs* (2015), <https://bigdata.fpf.org/wp-content/uploads/2015/12/Zimmer-Research-Ethics-in-the-Big-Data-Era.pdf>.

7. Narayanan & Zevenbergen, *supra* note 5, at 11.

8. See, e.g., Arvind Narayanan & Ed Felten, *No Silver Bullet: De-Identification Still Doesn't Work* (July 9, 2014), <http://randomwalker.info/publications/no-silver-bullet-de-identification.pdf> (arguing that de-identification is not effective at resisting adversarial attempts at re-identification).

9. See, e.g., Daniel Barth-Jones, *The Antidote for “Anecdata”: A Little Science Can Separate Data Privacy Facts from Folklore*, INFO/LAW (Nov. 21, 2014), <https://blogs.harvard.edu/infolaw/2014/11/21/the-antidote-for-anecdata-a-little-science-can-separate-data-privacy-facts-from-folklore/> (last visited Apr. 19, 2016) (arguing that the risk of re-identification is very small) (on file with the Washington and Lee Law Review); Khaled El Emam et al., *A Systematic Review of Re-Identification Attacks on Health Data*, 6 PLoS ONE 1, 11 (2011) (“[T]he evidence suggests that it would be prudent for data custodians to continue to de-identify their data using current best practices.”); see also Jules Polonetsky, Omer Tene & Kelsey Finch, *Shades of Gray: Seeing the Full Spectrum of Practical Data De-Identification*, SANTA CLARA L. REV. (forthcoming) (on file with authors).

database that contains the footprints of millions, or indeed billions, of data subjects. The second principle, *beneficence*, requires a delicate balance of risks and benefits to not only respect individuals' decisions and protect them from harm but also to secure their well-being. Difficult to deploy even in traditional research settings, such cost-benefit analysis is daunting in a data research environment where benefits could be probabilistic and incremental, and the definition of harm subject to constant wrangling between minimalists who reduce privacy to pecuniary terms and maximalists who view any collection of data as a dignitary infringement.<sup>10</sup>

In response to these developments, the Department of Homeland Security commissioned a series of workshops in 2011–2012, leading to the publication of the *Menlo Report on Ethical Principles Guiding Information and Communication Technology Research*.<sup>11</sup> That report remains anchored in the Belmont Principles, adapting them to the domain of computer science and network engineering, in addition to introducing a fourth principle, *respect for law and public interest*, to reflect the “expansive and evolving yet often varied and discordant, legal controls relevant for communication privacy and information assurance.”<sup>12</sup> In addition, on September 8, 2015, the U.S. Department of Health and Human Services and fifteen other federal agencies sought public comments to proposed revisions to the Common Rule.<sup>13</sup> The revisions, which address various changes in the ecosystem, include simplification of informed consent notices and exclusion of online surveys and

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10. Case C-362/14, Maximilian Schrems v. Data Protection Commissioner, 2015 E.C.R. 615, <http://curia.europa.eu/juris/document/document.jsf?docid=169195&doclang=EN>; see also Ryan Calo, *The Boundaries of Privacy Harm*, 86 IND. L.J. 1131, 1133 (2011) (elaborating on a concept of “privacy harms”).

11. DAVID DITTRICH & ERIN KENNEALLY, U.S. DEPT. OF HOMELAND SEC., *THE MENLO REPORT: ETHICAL PRINCIPLES GUIDING INFORMATION AND COMMUNICATION TECHNOLOGY RESEARCH* (2012), <https://www.predict.org/%5CPortals%5C0%5CDocuments%5CMenlo-Report.pdf>.

12. *Id.* at 5.

13. *NPRM for Revisions to the Common Rule*, U.S. DEPT OF HEALTH & HUMAN SERVS. (Sept. 8, 2015), <http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html> (last visited Apr. 19, 2016) (providing instructions for submitting comments on the NPRM) (on file with the Washington and Lee Law Review).

research of publicly available information as long as individual human subjects cannot be identified or harmed.<sup>14</sup>

For federally funded human subject research, the responsibility to evaluate whether a research project comports with the ethical framework lies with Institutional Review Boards (IRBs). Yet, one of the defining features of the data economy is that research is increasingly taking place outside of universities and traditional academic settings. With information becoming the raw material for production of products and services, more organizations are exposed to and closely examining vast amounts of often personal data about citizens, consumers, patients, and employees. This includes not only companies in industries ranging from technology and education to financial services and healthcare, but also non-profit entities, which seek to advance societal causes, and even political campaigns.<sup>15</sup>

Whether the proposed revisions to the Common Rule address some of the new concerns or exacerbate them is hotly debated. But whatever the final scope of the rule, it seems clear that while raising challenging ethical questions, a broad swath of academic research will remain neither covered by the rules nor subject to IRB review. Katie Shilton shows that academic researchers today have inconsistent views about how to handle these issues.<sup>16</sup> Currently, gatekeepers for ethical decisions range from private IRBs to journal publication standards, association guidelines, and peer review. A key question for further debate is whether there is a need for new principles as well as new structures for review of academic research that is not covered by the current or expanded version of the Common Rule.

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14. See ANNETTE MARKHAM & ELIZABETH BUCHANAN, ASSOCIATION OF INTERNET RESEARCHERS, ETHICAL DECISION-MAKING AND INTERNET RESEARCH RECOMMENDATIONS FROM THE AOIR ETHICS WORKING COMMITTEE (VERSION 2.0) 5–8 (2012), <http://aoir.org/reports/ethics2.pdf>. The original version of the recommendations, from 2002, is available at <http://aoir.org/reports/ethics.pdf>.

15. See Ira S. Rubinstein, *Voter Privacy in the Age of Big Data*, 2014 WISC. L. REV. 861, 866–85 (discussing the rise of data-driven political campaigns).

16. See KATIE SHILTON, EMERGING ETHICS NORMS IN SOCIAL MEDIA RESEARCH 1 (2015), <https://bigdata.fpf.org/wp-content/uploads/2015/12/Shilton-Emerging-Ethics-Norms-in-Social-Media-Research1.pdf> (discussing the changing consensus around ethical norms for social media research).

In *Beyond the Common Rule: Ethical Structures for Data Research in Non-Academic Settings*, we noted that even research initiatives that are not governed by the existing ethical framework should be subject to clear principles and guidelines. Whether or not a research project is federally funded seems an arbitrary trigger for ethical review. Urs Gasser and his co-authors note, “[T]he types of research activities increasingly conducted beyond the reach of traditional oversight due to the limited scope of the regulations in place.”<sup>17</sup> To be sure, privacy and data protection laws provide an underlying framework governing commercial uses of data with boundaries like consent and avoidance of harms. But, in many cases where informed consent is not feasible and where data uses create both benefits and risks, legal boundaries are more ambiguous and rest on vague concepts such as “unfairness”<sup>18</sup> or the “legitimate interests of the controller.”<sup>19</sup> This uncertain regulatory terrain could jeopardize the value of important research that could be perceived as ethically tainted or become hidden from the public domain to prevent scrutiny.<sup>20</sup> Concerns over data ethics “could diminish collaboration between researchers and private sector entities, restrict funding opportunities,” and lock research projects in corporate coffers contributing to the development of new products without furthering generalizable knowledge.<sup>21</sup>

In a piece he wrote for a *Stanford Law Review Online* symposium we organized in 2013,<sup>22</sup> Ryan Calo foresaw the

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17. Urs Gasser, Alexandra Wood, David R. O'Brien, Effy Vayena & Micah Altman, *Towards a New Ethical and Regulatory Framework for Big Data Research*, 72 WASH. & LEE L. REV. ONLINE 420, 424 (2016).

18. FTC Policy Statement on Unfairness, Appended to International Harvester Co., 104 F.T.C. 949, 1070 (1984); see 15 U.S.C. § 45(n) (2012).

19. *Opinion 06/2014 on the Notion of Legitimate Interests of the Data Controller Under Article 7 of Directive 95/46/EC* (Apr. 9, 2014), [http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp217\\_en.pdf](http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp217_en.pdf).

20. The Common Rule's definition of “research” is “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge*.” COMMON RULE, *supra* note 2 (emphasis added).

21. Jules Polonetsky, Omer Tene & Joseph Jerome, *Beyond the Common Rule: Ethical Structures for Data Research in Non-Academic Settings*, 13 COLO. TECH. L.J. 333, 335 (2015).

22. Symposium, *Privacy and Big Data: Making Ends Meet*, 66 STAN. L. REV. ONLINE 1 (2013), <http://www.stanfordlawreview.org/online/privacy-and-big-data>;

establishment of “Consumer Subject Review Boards” to address ethical questions about corporate data research.<sup>23</sup> Calo suggested that organizations should “take a page from biomedical and behavioral science” and create small committees with diverse expertise that could operate according to predetermined principles for ethical use of data. The idea resonated in the White House legislative initiative, the Consumer Privacy Bill of Rights Act of 2015, which requires the establishment of a Privacy Review Board to vet non-contextual data uses.<sup>24</sup> In Europe, the European Data Protection Supervisor has recently announced the creation of an Advisory Group to explore the relationships between human rights, technology, markets, and business models from an ethical perspective, with particular attention to the implications for the rights to privacy and data protection in the digital environment.<sup>25</sup>

Alas, special challenges hinder the adaptation of existing ethical frameworks, which are strained even in their traditional scope of federally funded academic research, to the fast-paced world of corporate research. For example, the categorical non-appealable decision making of an academic IRB, which is staffed by tenured professors to ensure independence, will be difficult to reproduce in a corporate setting. Yet, as Curtis Naser points out in his piece, any institution whose power falls short of an “IRB sledgehammer” becomes merely advisory.<sup>26</sup>

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see Jules Polonetsky & Omer Tene, *Privacy and Big Data: Making Ends Meet*, 66 STAN. L. REV. ONLINE 25 (2013).

23. See Ryan Calo, *Consumer Subject Review Boards: A Thought Experiment*, 66 STAN. L. REV. ONLINE 97, 102 (2013), <http://www.stanfordlawreview.org/online/privacy-and-big-data/consumer-subject-review-boards> (arguing that review boards would benefit consumers and industry).

24. WHITE HOUSE, ADMINISTRATION DISCUSSION DRAFT: CONSUMER PRIVACY BILL OF RIGHTS ACT OF 2015 § 103(c), <https://www.whitehouse.gov/sites/default/files/omb/legislative/letters/cpbr-act-of-2015-discussion-draft.pdf>.

25. EUR. DATA PROT. SUPERVISOR, EUROPEAN DATA PROTECTION SUPERVISOR DECISION (2015), <https://secure.edps.europa.eu/EDPSWEB/edps/site/mySite/Ethics> (“The external advisory group on the ethical dimensions of data protection . . . is hereby established.”).

26. Curtis Naser, *The IRB Sledge-Hammer, Freedom and Big-Data*, at 3 (2015), <https://bigdata.fpf.org/papers/the-irb-sledge-hammer-freedom-and-big-data/>.



To set the stage for possible adoption of IRB-like structures by corporate or nonprofit entities, which are currently outside the ambit of the Common Rule, we suggest posing five questions:

## *II. What Would Be Subject to Review?*

Even after its impending expansion, the Common Rule will likely remain incompatible with research that is not federally funded or does not constitute “big R research,” contributing to and advancing generalizable knowledge. As discussed above, it is important to extend some form of ethical review process to address such activities. At the same time, it is clear that IRBs cannot be charged with second guessing every operational business decision.

Which corporate research projects should become subject to ethical review? When does business analytics or A/B testing become “human subject research”? Should different rules apply to the same examination of the same dataset simply because the researchers have different affiliations or motives? Such disparate treatment could risk regulatory arbitrage—academics “laundering” research through corporations or nonprofits to escape the strictures of academic IRBs—or incentivize researchers to withdraw knowledge from the public sphere.

One solution would be to separate review of research projects geared toward publication from that of analytics intended for product development and improvement. Unfortunately, the line is not always clear. For example, would a project become research if a company publishes its results on its own website or a case study in a marketing document? And if a product or service is designed to improve health or advance a technology with broad societal implications, should ethical permissions differ depending on whether the results of an experiment are confidential or published? Some leading companies, large and small, are advancing ethical review models already, but can such models be formalized to have legal consequence or be feasible for start-ups and diverse business models?

## *III. Who Would Review?*

Should an internal corporate organ or an external body be charged with conducting an independent ethical review process? A private IRB would necessarily provide external stakeholders with less transparency about corporate processes than an external reviewer. Critics and consumer advocates may not view an internal review board as trustworthy or independent. Consequently, an internal review will necessitate mechanisms to ensure accountability, such as detailed documentation requirements and perhaps regulatory oversight and enforcement *ex post*. In addition, for it to be a meaningful gatekeeper, the composition and structure of an internal review board would have to be regulated. Moreover, a private review process would not contribute toward the creation of industry wide ethical standards and best practices.

At the same time, it would be difficult for organizations to hand over a high volume of strictly confidential business decisions, possibly exposing intellectual property, trade secrets, and their pipeline of innovative projects, to an external decision-making body. In addition, an external review board would lack the ability—or capacity—for ongoing monitoring of an organization's activities over time. Furthermore, with ethical decisions being made in a virtual vacuum, specific decisions may not reflect the full spectrum of risks and rewards underpinning an organization's broader operations.

An external review board would be an attractive option for an organization that lacks the resources, ability, or expertise to develop methodical internal processes. Such bodies could serve multiple companies in an industry or sector, thus solving the problem of small and medium size enterprises that lack the scale to create an internal review board. In addition, an industry-wide review board could help develop ethical standards and best practices, as well as an institutional memory that benefits the public at large.

Other questions concern the identity of members of a review board. Subject matter experts may have a better grip of the technological and business issues raised by a project but lack ethics expertise. Lawyers and ethics experts may master the legal and ethical framework but lack understanding of technical product detail or business strategy.

#### *IV. When Would Review Be Conducted?*

When should ethical gatekeepers engage with researchers to assess their project? Garfinkel points out that existing IRB practice requires a research experiment to be designed and approved *before* real world deployment.<sup>27</sup> Narayanan and Zevenbergen discuss the *retrospective* role of conference program committees, which are the arbiters of prestigious computer science research publications in conference proceedings.<sup>28</sup>

On the one hand, as several authors demonstrated, *ex ante* review of a research project enables a board to weigh in at the design stage, ensuring the research is ethically structured. Shilton discusses the consultative nature of review processes as well as the informal influence of peer review.<sup>29</sup> Dennis Hirsch and Jonathan King draw on experience with environmental law, noting “back-end environmental management strengthened compliance by the book but stifled innovation in environmental compliance itself.”<sup>30</sup> Early scrutiny would also ensure researchers do not waste valuable time and resources pursuing illegitimate trails. Importantly, as Narayanan and Zevenbergen note, where the putative harm of a project arises from *conducting* the research rather than its publication, a retrospective ethical review in conjunction with submission of the research for publication fails to prevent that harm.<sup>31</sup>

On the other hand, *ex post*, or better yet, *continuous*, review ensures that a project and its data trail are scrutinized at the dissemination stage and potentially when information is

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27. See Simson L. Garfinkel, *Beyond IRBs: Designing Ethical Review Processes for Big Data Research*, at 3 (2015), <https://bigdata.fpf.org/wp-content/uploads/2015/12/Garfinkel-Ethical-Framework.pdf> (“[A]n IRB framework that requires the procedures and scientific justification of the experiment to be designed in advance and approved by committee before any work can take place.”).

28. See Narayanan & Zevenbergen, *supra* note 5, at 9 (“In cases where the putative harm arises from *conducting* the research rather than its publication, the retrospective ethical review in fact fails to prevent that harm.”).

29. See SHILTON, *supra* note 16, at 3 (“[R]esearchers reported being challenged by their peers, including peer reviewers and funding agencies, and their colleagues on interdisciplinary teams.”).

30. Dennis D. Hirsch & Jonathan H. King, *Big Data Sustainability: An Environmental Management Systems Analogy*, 72 WASH. & LEE L. REV. ONLINE 406, 413 (2016).

31. Narayanan & Zevenbergen, *supra* note 5, at 9.

repurposed, shared, or reused. Gasser et al. note that ethical oversight is currently focused on the front end

emphasiz[ing] risk mitigation at the study design and data collection stages and, to a much lesser extent, those that arise in later stages such as dissemination and re-use stages. As advances in big data drive sharing and re-use of data by researchers, more of their activities will be subject to limited or, in some cases, no oversight.<sup>32</sup>

Garfinkel explains that the exploratory nature of data research, forming hypotheses only after conducting repeated analyses, simply does not fit an ethical review system that requires the procedures and scientific justification of an experiment to be vetted in advance.<sup>33</sup>

### V. Which Principles Would Apply?

In *Beyond the Common Rule*, we demonstrated that the substantive principles of Belmont and Menlo pair well with fundamental principles of privacy law, including the FTC's unfairness doctrine in the United States and the Data Protection Directive's legitimate interest test in the EU.<sup>34</sup> Neil Richards and Woody Hartzog suggest reviewing data research through the prism of trust doctrine, including by imposing on researchers a duty of loyalty.<sup>35</sup> The Information Accountability Foundation presents a detailed framework for corporate ethics that takes into account the expected benefits of an organization's big data inquiry, the array of stakeholders for whom processing may pose risks, and the measures that can be taken to mitigate those risks.<sup>36</sup> Similarly, in

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32. Gasser et al., *supra* note 17, at 426.

33. See Garfinkel, *supra* note 27, at 3 (“[B]ig data research is by its nature exploratory. . . . This approach to science doesn’t fit well within an IRB framework that requires the procedures and scientific justification of the experiment to be designed in advance and approved by committee before any work can take place.”).

34. See generally Polonetsky, Tene & Jerome, *supra* note 21.

35. See Neil M. Richards & Woodrow Hartzog, *Trusting Big Data Research*, DEPAUL L. REV. (forthcoming 2016), <https://bigdata.fpf.org/papers/trusting-big-data-research/> (“We believe that trust should be the lodestar of big data ethics and law, and that in order to promote trust, organizations must commit to Protection, Discretion, Honesty, and Loyalty.”).

36. See INFORMATION ACCOUNTABILITY FOUNDATION, BIG DATA ASSESSMENT

a previous White Paper, we suggested a structured process to guide businesses in weighing potential data benefits against privacy risks.<sup>37</sup>

Leading corporations have also contributed to the development of new principles for data research. Merck published a set of ethical privacy values that includes respect for individual privacy expectations, building and preserving trust, preventing privacy harms, and compliance with the letter and spirit of privacy and data protection laws around the world.<sup>38</sup> Intel's white paper, *Rethinking Privacy: Fair Information Practice Principles Reinterpreted*, highlights the enduring nature of the fair information practice principles and suggests new approaches to their implementation.<sup>39</sup> While much of this work is geared to address commercial analytics and product development, it could perhaps be replicated and extended to the arena of publishable data research.

## VI. Where Does the Line Cross for Data-Centered Research?

The need for ethical research rules is not restricted to experimentation involving personally identifiable information. The debate over the attacks reportedly launched in the wild by Carnegie Mellon University researchers against users of Tor demonstrates that even without a focus on—or arguably collection of<sup>40</sup>—personal data, research can have profound implications for individual

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FRAMEWORK AND WORKSHEET 5–14 (2015), <http://informationaccountability.org/wp-content/uploads/IAF-Big-Data-Ethics-Initiative-Part-B.pdf> (presenting an ethical assessment framework and worksheet).

37. See JULES POLONETSKY, OMER TENE & JOSEPH JEROME, FUTURE OF PRIVACY FORUM, BENEFIT-RISK ANALYSIS FOR BIG DATA PROJECTS 1–11 (2014), [https://www.ftc.gov/system/files/documents/public\\_comments/2014/08/00027-92420.pdf](https://www.ftc.gov/system/files/documents/public_comments/2014/08/00027-92420.pdf) (arguing that “[d]ecision-makers need to engage in a Data Benefit Analysis”).

38. See MERCK, 2014 CORPORATE RESPONSIBILITY REPORT 297–300, <http://www.merckresponsibility.com/ethics-transparency/global-privacy-program/> (last visited Apr. 19, 2016) (detailing Merck's Global Privacy Program) (on file with the Washington and Lee Law Review).

39. DAVID HOFFMAN & PAULA J. BRUENING, INTEL, RETHINKING PRIVACY: FAIR INFORMATION PRACTICE PRINCIPLES REINTERPRETED 3–19 (2015), <https://bigdata.fpf.org/wp-content/uploads/2015/11/Intel-Rethinking-Privacy.pdf>.

40. The debate about what is or is not personally identifiable information continues, for example, with respect to data points such as an IP address.

privacy and safety.<sup>41</sup> The *Black Hat USA* conference canceled a scheduled presentation of the CMU research, apparently due to ethical hurdles.<sup>42</sup> Narayanan and Zevenbergen discuss similar concerns with respect to the *Encore* project, a web-based censorship measurement co-opting unsuspecting users into the experiment.<sup>43</sup> On their website, *Encore* researchers state, “Our Institutional Review Board (IRB) has declined to formally review Encore because it isn’t considered human subjects research.”<sup>44</sup> While publishing their piece, the ACM SIGCOMM Program Committee added a strongly worded disclaimer, stating that it “found the paper controversial because some of the experiments the authors conducted raise ethical concerns” and concluding, “The PC endorses neither the use of the experimental techniques this paper describes nor the experiments the authors conducted.”<sup>45</sup>

Non-data related ethical concerns are not unique to big R research. As they develop products, companies frequently test and experiment in ways unrelated to the collection and use of personal information. They A/B test products, experiment with new drugs,

41. See Ed Felten, *Why Were CERT Researchers Attacking Tor?*, FREEDOM TO TINKER (July 31, 2014), <https://freedom-to-tinker.com/blog/felten/why-were-cert-researchers-attacking-tor/> (last visited Apr. 12, 2016) (detailing the ethical concerns related to a large-scale identification attack on Tor hidden services by researchers) (on file with the Washington and Lee Law Review).

42. See Andrea Peterson, *Why Was the Black Hat Talk on Tor De-Anonymization Mysteriously Canceled?*, WASH. POST (July 14, 2014), <https://www.washingtonpost.com/news/the-switch/wp/2014/07/24/why-was-the-black-hat-talk-on-tor-de-anonymization-mysteriously-canceled/> (last visited Apr. 12, 2016) (“[T]he description of the talk said the researchers had tested their technique ‘in the wild.’ Some privacy advocates took that to mean they were experimenting with de-anonymizing data from Tor users without their consent—something which experts say raises some legal and ethical concerns.”) (on file with the Washington and Lee Law Review).

43. Narayanan & Zevenbergen, *supra* note 5, § 5; see Sam Burnett & Nick Feamster, *Encore: Lightweight Measurement of Web Censorship with Cross-Origin Requests*, ACM SIGCOMM 653, 653 (Aug. 2015), <http://conferences.sigcomm.org/sigcomm/2015/pdf/papers/p653.pdf> (“[P]resent[ing] Encore, a system that harnesses cross-origin requests to measure Web filtering from a diverse set of vantage points without requiring users to install custom software, enabling longitudinal measurements from many vantage points.”).

44. Sam Burnett & Nick Feamster, *Encore: Measure Web Censorship*, <https://encore.noise.gatech.edu/faq.html> (last visited Mar. 12, 2016) (on file with the Washington and Lee Law Review).

45. Burnett & Feamster, *supra* note 43, at 653.

and closely examine the performance of new services. Some of these activities are governed specifically by a range of regulatory agencies handling safety issues, including the Food and Drug Administration, Department of Transportation, Consumer Product Safety Commission, Consumer Financial Protection Bureau, and, more generally, the FTC. This Article focuses specifically on issues related to data-driven research, which is an area where the notion of harm is still hotly debated and both benefit and risk are typically intangible.

We suggest that, regardless of whether or not personally identifiable information is used, ethical principles should extend to research affecting individuals. As the field of data ethics develops and grows, policymakers should seek to harmonize the principles and procedures governing academic research, corporate research, and corporate product development using personal data, as well as research projects affecting individuals in real ways.