

1-1-2016

# Need for Informed Consent in the Age of Ubiquitous Human Testing

Caitlyn Kuhs

---

## Recommended Citation

Caitlyn Kuhs, *Need for Informed Consent in the Age of Ubiquitous Human Testing*, 49 Loy. L.A. L. Rev. 245 (2016).  
Available at: <https://digitalcommons.lmu.edu/llr/vol49/iss1/6>

This Notes is brought to you for free and open access by the Law Reviews at Digital Commons @ Loyola Marymount University and Loyola Law School. It has been accepted for inclusion in Loyola of Los Angeles Law Review by an authorized administrator of Digital Commons@Loyola Marymount University and Loyola Law School. For more information, please contact [digitalcommons@lmu.edu](mailto:digitalcommons@lmu.edu).

# NEED FOR INFORMED CONSENT IN THE AGE OF UBIQUITOUS HUMAN TESTING

*Caitlyn Kuhs\**

## I. INTRODUCTION

In 2011, executives at Facebook<sup>1</sup> discovered research suggesting that the social networking site generated unhappiness among its users.<sup>2</sup> This discovery prompted Facebook to conduct its own study utilizing its users as test subjects.<sup>3</sup> Facebook manipulated approximately 700,000 users' News Feeds<sup>4</sup> by reducing either positive or negative content.<sup>5</sup> It then assessed how this impacted the users' own behavior on the website.<sup>6</sup> The study found that a "larger percentage of words in people's status updates<sup>7</sup> were negative and a smaller percentage were positive" when the positive content that the users saw in their News Feeds was reduced.<sup>8</sup> Similarly, when negative content was reduced, users employed more positive

---

\* J.D. Candidate, May 2016, Loyola Law School, Los Angeles; B.S. Business: Marketing, Indiana University, May 2010. Thank you to my advisor, Professor Karl Manheim, for providing me with invaluable guidance throughout the writing process, and to the editors and staff of the *Loyola of Los Angeles Law Review* for their scrupulous edits.

1. Facebook is a social networking site that connects users via the Internet, consisting of 1.59 billion monthly active users. *Company Info*, FACEBOOK NEWSROOM, <https://newsroom.fb.com/company-info/> (last updated Dec. 31, 2015). Social networking is the "practice of using a Web site or other interactive computer service to expand one's business or social network." *Doe v. Myspace, Inc.*, 528 F.3d 413, 415 (5th Cir. 2008).

2. Libby Copeland, *The Anti-Social Network: By Helping Other People Look Happy, Facebook Is Making Us Sad*, SLATE (Jan. 26, 2011, 4:51 PM), [http://www.slate.com/articles/double\\_x/doublex/2011/01/the\\_antisocial\\_network.html](http://www.slate.com/articles/double_x/doublex/2011/01/the_antisocial_network.html).

3. See Adam D.I. Kramer et al., *Experimental Evidence of Massive-Scale Emotional Contagion Through Social Networks*, 111 PROC. NAT'L ACAD. SCI. 8788 (2014).

4. The Facebook News Feed "filters posts, stories, and activities undertaken by friends . . . [and] is the primary manner by which people see content that friends share." *Id.*

5. *Id.*

6. *Id.* at 8789.

7. Status updates are "undirected text-based messages that a user's social contacts (Facebook friends) may view on their own News Feed." Lorenzo Coviello et al., *Detecting Emotional Contagion in Massive Social Networks*, 9 PLOS ONE 1, 2–3 (2014).

8. Kramer et al., *supra* note 3, at 8789.

language.<sup>9</sup> This may be the first time that a social media website engaged in overt human subjects research of this kind, or “any manipulation, observation, or other study of a human being—or of anything related to that human being that might subsequently result in manipulation of that human being—done with the intent of developing new knowledge and which differs in any form from customary medical (or other professional) practice.”<sup>10</sup>

The study stated that users had given informed consent<sup>11</sup> based on Facebook’s terms of use agreement (“Data Use Policy”).<sup>12</sup> At the time of the research study, however, Facebook’s Data Use Policy “did not mention the use of users’ data for research, testing, or analysis.”<sup>13</sup> Four months after the research concluded, Facebook updated the section titled *How We Use the Information We Receive* to state: “[I]n addition to helping people see and find things that you do and share, we may use the information we receive about you . . . for internal operations, including troubleshooting, data analysis, testing, *research* and service improvement.”<sup>14</sup> Since this relevant update was not yet implemented at the time of the study, it is unlikely that users had any expectations that their information would be used in such a way—to conduct sociological research and influence behavior. This illustrates how the “current self-regulatory regime of contracts between the social networking sites and its users

---

9. *Id.*

10. Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 166 (1998) (citing Robert J. Levine, *The Boundaries Between Biomedical or Behavioral Research and the Accepted and Routine Practice of Medicine*, in THE BELMONT REPORT app. vol. I., at 1-1 to -6 (1979)). Research “designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge” which “consists of theories, principles, or relationships (or the accumulation of data on which they may be used) that can be corroborated by accepted scientific observation and inference.” *Id.* (citations omitted).

11. “Informed consent is a process during which the researcher accurately describes the project and its risks to subjects and they accept the risks and agree to participate or decline.” Michael Bailey et al., *The Menlo Report: Ethical Principles Guiding Information and Communication Technology Research*, U.S. DEP’T OF HOMELAND SEC. 10 (2012), <http://www.dhs.gov/sites/default/files/publications/CSD-MenloPrinciplesCORE-20120803.pdf> [hereinafter *Menlo Report*].

12. Kramer et al., *supra* note 3, at 8789; see *Data Use Policy*, FACEBOOK, [https://www.facebook.com/full\\_data\\_use\\_policy](https://www.facebook.com/full_data_use_policy) (last updated Jan. 30, 2015).

13. Complaint, Request for Investigation, Injunction, and Other Relief Submitted by The Electronic Privacy Information Center, In the Matter of Facebook, Inc., FTC File No. 092-3184, ELEC. PRIVACY INFO. CTR. 4 (2012), <https://epic.org/privacy/internet/ftc/facebook/psycho/Facebook-Study-Complaint.pdf> [hereinafter EPIC Complaint].

14. *Id.*; *Data Use Policy*, *supra* note 12 (emphasis added).

via privacy policy is insufficient to protect the interests of the users.”<sup>15</sup>

Recognizing this lapse in consumer care, the Electronic Privacy Information Center (EPIC) filed a complaint with the Federal Trade Commission (FTC).<sup>16</sup> This complaint urged the FTC to investigate Facebook’s practices regarding data collection and sharing in the context of the 2011 study, and to enjoin all deceptive practices.<sup>17</sup> Without specific regulation, these self-regulatory missteps are redressable only on a case-by-case basis.<sup>18</sup> Thus, this Note demonstrates the need for structured informed consent standards in social media-based human subjects research in order to adapt to the new research arena that the Facebook study illuminated.

This Note discusses the privacy implications of online human subjects research and the need for standardized regulation of informed consent for social media-sourced research to protect users’ privacy interests and freedom to refuse consent. First, Section II addresses the current state of online privacy and Data Use Policies’ current role as the sole basis for informed consent to social media-based research. Second, Section III details the informed consent standards in human subjects research, outlining the reports that shaped current standards and the subsequent implications thereof. Next, Section IV illuminates the imbalance in online regulation and human subjects research standards, demonstrating the need for regulatory reform for online research. Finally, Section V suggests regulatory reform that expands Institutional Review Board standards to online research, and asserts that data use policies should never form the basis for informed consent in research that intends to manipulate behavior.

---

15. Connie Davis Powell, “*You Already Have Zero Privacy. Get Over It!*” *Would Warren and Brandeis Argue for Privacy for Social Networking?*, 31 PACE L. REV. 146, 147 (2011).

16. EPIC Complaint, *supra* note 13.

17. *Id.* at 13.

18. A report filed by the FTC calls largely for self-regulation, and thus actions like the EPIC Complaint must be filed each time an outside party wishes to assert a claim against organizations conducting research outside the purview of Institutional Review Boards. *See generally* FED. TRADE COMM’N, PROTECTING CONSUMER PRIVACY IN AN ERA OF RAPID CHANGE: RECOMMENDATIONS FOR BUSINESSES AND POLICYMAKERS (2012) [hereinafter FTC REPORT] (recommending that businesses act to implement best practices to protect consumers’ private information, and articulating those best practices).

## II. PRIVACY IMPLICATIONS OF SOCIAL MEDIA USE

Social media has been a major source of widespread informational growth. With billions of social media users worldwide,<sup>19</sup> social media serves as an attractive resource for human subjects researchers. Due to the vagueness of social media's Data Use Policies and procedures, however, any research benefits of utilizing social media currently appear to take priority over the privacy that social media platforms purport to afford their users.

### A. Data Use Policies

Social networking websites' Data Use Policies are the most commonly used standard-form contracts, as billions of people use the sites worldwide.<sup>20</sup> Data Use Policies exemplify current standard adhesion contracts, where consumers accept the terms of a contract on a take-it-or-leave-it basis, and which are created and implemented entirely by the website owners.<sup>21</sup> With adhesion contracts, the user "has no choice but to acquiesce to the terms of the stronger party; the transaction is 'one not of haggle or cooperative process but rather of a fly and flypaper.'"<sup>22</sup>

In these agreements, most social media companies claim the right to revise their Data Use Policies at any time without providing notice to the user.<sup>23</sup> As a result of this approach, social media companies grant themselves freedom to use consumer data when their users assent to Data Use Policies that may be outdated. Thus, adhesion contracts pose an inherent problem to the notion of informed consent in social media-based research where users antecedently "consent" to terms that have not yet been added to the Data Use Policy.

---

19. See *Company Info*, *supra* note 1.

20. Michael L. Rustad & Maria Vittoria Onufrio, *Reconceptualizing Consumer Terms of Use for a Globalized Knowledge Economy*, 14 U. PA. J. BUS. L. 1085, 1086 (2012).

21. *Id.* at 1096.

22. *Id.* at 1098 (citing Arthur Allen Leff, *Contract as Thing*, 19 AM. U. L. REV. 131, 143 (1970)).

23. *Id.* at 1086–87.

## 1. Types of Agreements

Social networking websites typically use a combination of clickwrap and browsewrap agreements.<sup>24</sup> These agreements often include these revision-at-will clauses discussed in the preceding paragraph, which require users to continually revisit the agreement in order to maintain awareness of all terms and conditions.<sup>25</sup> Users, then, “pay” for “free” use of social media by tendering their personal information.<sup>26</sup> Users might not be so willing to surrender their privacy rights if they were aware of the extent to which their information is used.<sup>27</sup>

## 2. Consent to Standard Terms

Consent validates “intervention into what is otherwise a private affair.”<sup>28</sup> Typically, users consent to terms they have not read, thus giving the drafter an informational advantage called “information asymmetry.”<sup>29</sup> “Companies use fine print, legalese, and excess verbiage which render their contracts incomprehensible.”<sup>30</sup> Users then lack the requisite knowledge to make an informed choice to consent when these standard-form contracts become so complex that users miss or misunderstand information that would materially affect

---

24. These require that the user assent to the provider’s terms of use upon first accessing the website. Some websites bypass the formality by indicating that users are bound by the terms simply by using the website. *Id.* at 1112–13, 1116. Clickwrap agreements generally require the user to assent to the contract terms by checking a box on the website stating that the user agrees to the terms and conditions of the site in order to access it. *Id.* at 1105. Browsewrap agreements, on the other hand, do not require the user to expressly assent to the terms, but rather assent simply by accessing the website. *Id.* at 1106–07.

25. Nancy S. Kim, *Boilerplate and Consent*, 17 GREEN BAG 2d 293, 303 (2014).

26. Facebook’s market capitalization is currently over \$200 billion. Tim Bradshaw, *Facebook Market Value Tops \$200bn*, FIN. TIMES (Sept. 9, 2014, 12:00 AM), <http://www.ft.com/intl/cms/s/0/ecc0f050-37a3-11e4-bd0a-00144feabdc0.html#axzz3RgnzAtzq>. Assuming that each of its roughly one billion users has the same value to Facebook, then the average user would be worth approximately \$200 to the site. *See* George Anders, *You’re Worth \$128 on Facebook; Sorry About That LinkedIn Drop*, FORBES (Feb. 7, 2014, 6:47 AM), [http://www.forbes.com/sites/georgeanders/2014/02/07/youre-worth-128-on-facebook-sorry-about-that-linkedin-drop/?\\_suid=1423882704248030783189879730344](http://www.forbes.com/sites/georgeanders/2014/02/07/youre-worth-128-on-facebook-sorry-about-that-linkedin-drop/?_suid=1423882704248030783189879730344). Much of this value lies in the personal information Facebook collects from users and resells to advertisers. Not all Facebook users are equally valuable, however, as the site has both “star users” who frequently create content on the site and “worthless accounts” that rarely engage with the site. *Id.* Assuming that all users are equally valued, however, this \$200 (and growing) rate is the value of each user’s privacy he or she exchanges for “free” use of the site.

27. *See* Kim, *supra* note 25, at 301.

28. *Id.* at 295.

29. *Id.*

30. *Id.* at 303.

their understanding of the contract terms.<sup>31</sup> Additionally, users are affected by heuristic bias—“the cognitive limitations or ‘bounded rationality’ of human beings [that] impedes decisionmaking [sic].”<sup>32</sup> This bias demonstrates that people selectively read information that is relevant at the time of reading, and will miss important terms that are not relevant in that particular moment.<sup>33</sup>

Thus, the heuristic bias makes informed consent to standard-form Data Use Policies a difficult proposition.<sup>34</sup> Users are often unaware of the terms, and thus are unaware of the impact of those terms.<sup>35</sup> Either users will have to accommodate to a restricted expectation of choice regarding privacy, as has generally been the case, or Data Use Policies must become more visible and transparent to users so that they may make an informed choice regarding the information they wish to share with social media companies.

### *B. Data Collection and Consent to Research*

The degree of informed consent required depends on the data collection process. Data collection can be either passive or active.<sup>36</sup> Passive data collection gathers users’ autonomous information, while active data collection asks users to submit answers to specific questions.<sup>37</sup> Facebook’s data collection is typically passive; it monitors the information about, and provided by, the users rather than directly seeking answers to questions.<sup>38</sup> Because passive data collection is less obvious to the user, it is also potentially more intrusive.

Consent to research can also be either passive or active.<sup>39</sup> Active consent requires the researcher to obtain express consent to use the user’s information, while passive consent assumes consent to research unless the user objects.<sup>40</sup> However, regardless of whether a

---

31. *Id.* at 296.

32. *Id.* at 295 (citing MARGARET JANE RADIN, *BOILERPLATE: THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW* 8–9 (2013)).

33. *Id.*

34. *Id.* at 296.

35. *Id.* at 298.

36. Lauren B. Solberg, *Complying with Facebook’s Terms of Use in Academic Research: A Contractual and Ethical Perspective on Data Mining and Informed Consent*, 82 *UMKC L. REV.* 787, 791 (2014).

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.* at 791–92.

researcher seeks passive or active consent, a user may not even see the request. Thus, the user may miss the opportunity to voluntarily consent or refuse to consent.<sup>41</sup> As such, researchers must be cautious if relying on passive consent, and should be certain any lack of response is not due to the fact that the user was unaware of the consent request.<sup>42</sup>

### C. FTC Report and Do Not Track Technology

The FTC Act establishes unfair and unlawful methods of competition.<sup>43</sup> It defines objectives and procedures regarding unfair or deceptive acts or practices by businesses or individuals in or affecting interstate commerce.<sup>44</sup> Unfair practices are acts that “cause[] or [are] likely to cause substantial injury to consumers which [are] not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.”<sup>45</sup>

In March of 2012, the FTC released a report suggesting best privacy practices for businesses to implement in order to protect online users’ private information.<sup>46</sup> The report made three main suggestions: (1) privacy should be the default expectation and should be implemented at every stage of product development; (2) consumers should be given the “ability to make decisions about their data at a relevant time and context, including through a Do Not Track mechanism, while reducing the burden on businesses of providing unnecessary choices;” and (3) transparency must be greater among businesses using consumer data and must describe the nature of that use.<sup>47</sup> These suggestions are part of a growing effort to adopt “privacy by design” as best practices.<sup>48</sup>

---

41. *Id.* at 792.

42. *Id.*

43. Federal Trade Commission Act, 15 U.S.C. § 45 (2006).

44. *Id.*

45. *Id.* § 45(n).

46. *See* FTC REPORT, *supra* note 18.

47. *Id.* at i.

48. *See, e.g.*, Edith Ramirez, Comm’r, Fed. Trade Comm’n, Remarks at the Privacy by Design Conference, FED. TRADE COMM’N (June 13, 2012), [https://www.ftc.gov/sites/default/files/documents/public\\_statements/privacy-design-and-new-privacy-framework-u.s.federal-trade-commission/120613privacydesign.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/privacy-design-and-new-privacy-framework-u.s.federal-trade-commission/120613privacydesign.pdf) (“Privacy by design continues to be the buzz concept of the day in the privacy world. And it is an important part of what the U.S. Federal Trade Commission and many other privacy authorities around the globe now advocate.”); Kashmir Hill, *Why ‘Privacy by Design’ Is the New Corporate Hotness*, FORBES (July 28, 2011, 1:23 PM),



The FTC report also recommended implementation of Do Not Track technology, which allows consumers to choose whether or not they want their data to be accessed by online companies.<sup>49</sup> According to the FTC report, Do Not Track technology should include five key principles:

First, a Do Not Track system should be implemented universally to cover all parties that would track consumers. Second, the choice mechanism should be easy to find, easy to understand, and easy to use. Third, any choices offered should be persistent and should not be overridden if, for example, consumers clear their cookies or update their browsers. Fourth, a Do Not Track system should be comprehensive, effective, and enforceable. It should opt consumers out of behavioral tracking through any means and not permit technical loopholes. Finally, an effective Do Not Track system should go beyond simply opting consumers out of receiving targeted advertisements; it should opt them out of collection of behavioral data for all purposes other than those that would be consistent with the context of the interaction.<sup>50</sup>

This report demonstrated the FTC's strong recognition that consumer privacy is important and that businesses must revise their practices to avoid intruding into consumers' privacy.<sup>51</sup> Facebook has implemented some of these suggestions and will provide a user with information collected about him or her and the nature of that collection if that user requests it.<sup>52</sup> Additionally, many web browsers such as Firefox and Safari have implemented Do Not Track technology, giving consumers more freedom to choose when and if their information is used.<sup>53</sup> It is important to note, however, that Do

---

<http://www.forbes.com/sites/kashmirhill/2011/07/28/why-privacy-by-design-is-the-new-corporate-hotness/>.

49. See FTC REPORT, *supra* note 18.

50. *Id.* at 53.

51. However, the report largely recommended self-regulatory measures. *See id.* at viii.

52. *Accessing Your Facebook Data*, FACEBOOK, <https://www.facebook.com/help/405183566203254> (last visited Oct. 19, 2014) ("This includes a lot of the same information available to you in your account and activity log, including your Timeline info, posts you have shared, messages, photos and more. Additionally, it includes information that is not available simply by logging into your account, like the ads you have clicked on, data like the IP addresses that are logged [into] when you log into or out of Facebook, and more.").

53. FTC REPORT, *supra* note 18, at 53–54.

Not Track technology merely signals to the website operator that the user does not wish to be tracked. This does not prevent tracking in and of itself, so the site owners are still left with the ultimate decision of whether or not to honor users' wishes expressed through Do Not Track procedures.<sup>54</sup>

Recent changes in Facebook's privacy policies may also be a result of an action the FTC filed against Facebook.<sup>55</sup> The complaint listed several situations where Facebook expressly claimed to maintain user privacy in a specific manner and then subsequently failed to follow its own standards.<sup>56</sup> This complaint resulted in a settlement, which required Facebook to make a number of changes, including that it: (1) no longer misrepresent users' privacy or information security, (2) attain users' "affirmative express consent" before making any changes that override their privacy preferences, and (3) implement a "comprehensive privacy program."<sup>57</sup> While these changes undeniably aid data use transparency,<sup>58</sup> they do not resolve privacy with regards to research consent concerns since such issues remain largely unregulated and redressable only on a case-by-case basis.<sup>59</sup>

### III. INFORMED CONSENT STANDARDS IN HUMAN SUBJECTS RESEARCH

Informed consent standards in medical research look very different from consent to Data Use Policies. Unlike the general rules of contracts, human subjects research often poses greater ethical and medical risks, and thus greater need for closer inspection and regulation of the nature and extent of informed consent.<sup>60</sup> However,

---

54. *See id.* at viii.

55. *See Facebook Settles FTC Charges That It Deceived Consumers by Failing to Keep Privacy Promises*, FED. TRADE COMM'N (Nov. 29, 2011), <http://www.ftc.gov/news-events/press-releases/2011/11/facebook-settles-ftc-charges-it-deceived-consumers-failing-keep> [hereinafter *Facebook Settles FTC Charges*]. The FTC had previously filed a similar complaint against Google. *See FTC Charges Deceptive Privacy Practices in Googles Rollout of Its Buzz Social Network: Google Agrees to Implement Comprehensive Privacy Program to Protect Consumer Data*, FED. TRADE COMM'N (Mar. 30, 2011), <http://www.ftc.gov/news-events/press-releases/2011/03/ftc-charges-deceptive-privacy-practices-googles-rollout-its-buzz>.

56. *Facebook Settles FTC Charges*, *supra* note 55.

57. *Id.*

58. Interestingly, though, the Facebook research was released after this settlement.

59. *See* FTC REPORT, *supra* note 18.

60. *See* Dan O'Connor, *The Apomediated World: Regulating Research When Social Media Has Changed Research*, 41 J.L. MED. & ETHICS 470, 470 (2013) ("[E]ven when the regulations

social media-based research is a recent development, and the current medical research regulation does not extend far enough to resolve the privacy problems presented by advances in research technology.<sup>61</sup>

#### A. *Consenting to Research*

It is possible that users have become accustomed to expect limited online privacy,<sup>62</sup> yet behavioral research imposes additional, and oftentimes more severe, implications beyond that of ordinary website interactions. Informed consent arose in the medical treatment context in cases of battery, and later negligence, where doctors failed to obtain consent from their patients prior to initiating a medical procedure.<sup>63</sup> Physicians in this context are held to the informed consent standard of what is customary in that particular field of medicine, or alternatively, what a “reasonable person in the patient’s position would consider material and would want to know.”<sup>64</sup> In the context of experimentation and research, informed consent has taken a different theoretical approach, adopting the “reasonable volunteer” standard.<sup>65</sup> This provides that:

The extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the

---

seem most obviously to be about protecting subjects from harm, it is possible to say, also, that they are protecting subjects from the researchers whose work entails the possibility of harm to, or exploitation of, their subjects.”)

61. *See id.* at 474 (“[T]he existing rules for the protection of human research subjects—rules outlined in The Belmont Report, enshrined in the “Common Rule,” and enforced in part by [the Office of Human Research Protections]—do not always clearly apply to medical research using online social networks.”).

62. *See Powell, supra* note 15, at 164 (“People have really gotten comfortable not only sharing more information and different kinds, but more openly and with more people. That social norm is just something that has evolved over time.” (citing Marshall Kirkpatrick, *Facebook’s Zuckerberg Says the Age of Privacy Is Over*, READWRITEWEB (Jan. 9, 2010), [http://www.readwriteweb.com/archives/facebooks\\_zuckerberg\\_says\\_the\\_age\\_of\\_privacy\\_is\\_ov.php](http://www.readwriteweb.com/archives/facebooks_zuckerberg_says_the_age_of_privacy_is_ov.php))); *see also* Samuel Warren & Louis Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 218 (1890) (“The right to privacy ceases upon the publication of the facts by the individual, or with his consent.”).

63. Morin, *supra* note 10, at 159–60.

64. *Id.* at 160.

65. *Id.* at 176.

subjects should understand clearly the range of risk and the voluntary nature of participation.<sup>66</sup>

This reasonable volunteer standard was set forth in *The Belmont Report: Ethical Principles and Guidelines for Research Involving Human Subjects* (the “Belmont Report”), “which attempts to summarize the basic ethical principles” identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.<sup>67</sup> This and other regulations, such as the Common Rule,<sup>68</sup> form the foundation of informed consent standards for human subjects research today.

### 1. The Common Rule and Other Existing Regulation

The need for ethical standards in human subjects research first entered the public discourse during World War II.<sup>69</sup> The Nuremberg Code addressed experimentation on Nazi concentration camp prisoners and set forth standards for conducting human subjects research.<sup>70</sup> Still, unethical research continued.<sup>71</sup> This lack of care gave rise to the need for federal action.<sup>72</sup>

#### *a. The Belmont Report*

The Belmont Report presents three basic ethical principles to consider in human subjects research:<sup>73</sup> (1) respect for persons, (2) beneficence, and (3) justice.<sup>74</sup> The idea of respect for persons concerns respecting subjects’ autonomy, which is one of the most

---

66. *Id.* (citing Belmont Report, 44 Fed. Reg. 23192, 23196 (Apr. 18, 1979) (to be codified at 45 C.F.R. pt. 46)).

67. Belmont Report, 44 Fed. Reg. at 23192.

68. The Common Rule is discussed in the following Section. *See infra* Section III.A.1.

69. Belmont Report, 44 Fed. Reg. at 23192.

70. *Id.*

71. Morin, *supra* note 10, at 175. Notable examples include the Tuskegee Syphilis Study, where “hundreds of black men with syphilis were monitored over time but not appropriately treated despite the availability of penicillin.” *Id.* The persistent unethical research exemplified here can be likened to our current situation, where lack of federal reform leaves much room for unconsented research conducted online.

72. *Id.*

73. The report did not address social experimentation, but rather only specifically addressed biomedical and behavioral research. *See id.* The 2011 Facebook study, and similar social media-based research, may be viewed as either behavioral research or social experimentation; therefore, the Belmont Report’s ethical considerations are relevant in determining the appropriate applicable standards to social-media based human subjects research.

74. Belmont Report, 44 Fed. Reg. at 23193.

important considerations in satisfying informed consent.<sup>75</sup> An autonomous person is “an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.”<sup>76</sup> Alternatively, lack of respect for a person’s autonomy “repudiate[s] that person’s considered judgments, [] den[ies] an individual the freedom to act on those considered judgments, or [] withhold[s] information necessary to make a considered judgment, when there are no compelling reasons to do so.”<sup>77</sup> Beneficence and justice require the researcher to do no harm to the subjects, and to treat everyone equally and fairly.<sup>78</sup>

The Belmont Report also distills informed consent into three elements: (1) information, (2) comprehension, and (3) voluntariness.<sup>79</sup> Research subjects should be given sufficient information, including the purpose of the study, risks and benefits, and a statement giving the subject the opportunity to ask questions or withdraw from the study.<sup>80</sup> The Belmont Report recognizes that, in some cases, full disclosure of information would impair the results of the study.<sup>81</sup> In such cases, incomplete disclosure is justified only if: “(1) [i]ncomplete disclosure is truly necessary to accomplish the goals of the research, (2) [t]here are no undisclosed risks to subjects that are more than minimal, and (3) [t]here is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them.”<sup>82</sup> Additionally, it is important to “distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.”<sup>83</sup> Researchers are also responsible for ensuring that subjects understand the information provided, and that subject participation in the study is voluntary.<sup>84</sup> This requirement negates the idea, absent narrow exceptions, that it is permissible for a subject to be unaware that he or she was ever a participant, as was the case in the Facebook study. Where a subject is unknowingly

---

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.* at 23194.

79. *Id.* at 23195.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

researched upon, unless the study meets one of the few exceptions, consent is neither voluntary nor sufficient.

*b. The Common Rule*

The principles set forth in the Belmont Report were first codified almost a decade later in a U.S. Department of Health and Human Services (HHS) regulation known as the Common Rule.<sup>85</sup> Fifteen federal departments and agencies have subsequently codified the Common Rule.<sup>86</sup> The Common Rule “requires that federally funded investigators in most instances obtain and document the informed consent of research subjects, and describes requirements for institutional review board membership, function, operations, research review, and recordkeeping.”<sup>87</sup> It applies to all research conducted by fifteen federal departments and agencies, as well as to any institution claiming Federalwide Assurance (“FWA”)<sup>88</sup> for the protection of human subjects by adopting the regulations set forth in the Common Rule.<sup>89</sup> The regulations are intended to supplement any existing federal laws or regulations that concern the protection of human subjects, and otherwise do not affect or preempt applicable state, local, or foreign laws.<sup>90</sup> Institutional Review Boards (IRBs)<sup>91</sup> serve the purpose of enforcing the Common Rule in federal research by approving the ethicality of the study, setting informed consent standards in accordance with the Common Rule, or alternatively,

---

85. Protection of Human Subjects, 45 C.F.R. pt. 46 (2014).

86. *Comments of the Electronic Privacy Information Center to the Department of Homeland Security*, ELEC. PRIVACY INFO. CTR. (Feb. 27, 2012), [https://www.epic.org/open\\_gov/apa/EPIC-DHS-Menlo-Report-Comments-FINAL.pdf](https://www.epic.org/open_gov/apa/EPIC-DHS-Menlo-Report-Comments-FINAL.pdf) [hereinafter *EPIC Comments*].

87. *Id.* (quoting Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44512 (July 26, 2011) (to be codified at 45 C.F.R. pt. 46)).

88. *See generally Federalwide Assurance (FWA) for the Protection of Human Subjects*, U.S. DEP’T OF HEALTH AND HUM. SERVS., <http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html> (last updated June 17, 2011) (“All of the Institution’s human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.”).

89. *See* Leili Fatehi & Ralph F. Hall, *Enforcing the Rights of Human Sources to Informed Consent and Disclosures of Incidental Findings from Biobanks and Researchers: State Mechanisms in Light of Broad Regulatory Failure*, 13 MINN. J.L. SCI. & TECH. 575, 585 (2012).

90. 45 C.F.R. § 46.101(e)–(g) (2014).

91. IRBs are established in accord with the Common Rule, and review and set constraints on research in accordance with the Common Rule to ensure risk is minimized. *Id.* § 46.102(g)–(i).

waiving the informed consent requirement in certain circumstances.<sup>92</sup> The Common Rule applies to “all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.”<sup>93</sup> The federal agency or department that typically handles research activity is also responsible for following Common Rule standards. For example, IRB approval would be necessary for “Investigational New Drug requirements administered by the Food and Drug Administration.”<sup>94</sup>

Research involving the collection of “existing data . . . if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects,” is exempt from Common Rule regulation.<sup>95</sup> For example, even where data is de-identified, if it is coded in such a way that the subject may be subsequently identified through identifiers linked to the subject, then this exemption will not apply.<sup>96</sup> Thus, when researchers collect pre-existing data from social media, the information is traceable to the subject such that this exemption would not apply.

Additionally, where the data is “publicly available,” the research is not subject to IRB approval.<sup>97</sup> Traditionally, this was intended to apply to public sources of data, such as census data.<sup>98</sup> Information posted to Facebook, therefore, is arguably not “public” for the purposes of the Common Rule, as any given social media user has control over who he or she wishes to see the information posted to the site.<sup>99</sup>

If research is not exempt from IRB approval, a researcher must seek informed consent through a written consent form in circumstances that “provide the prospective subject or the [legally

---

92. *Id.* § 46.109; *see also id.* § 46.101(i).

93. *Id.* § 46.101.

94. *Id.* § 46.102.

95. *Id.* § 46.101(b)(4).

96. Paul J. Andreason, M.D., *When Is It “Human Subjects Research?” Focus on Social-Behavioral Research*, PROTECTING HUMAN SUBJECTS (Dec. 1, 2007), <http://humansubjects.energy.gov/other-resources/07hswg-mtg/andreason.pdf>.

97. 45 C.F.R. § 46.101(b)(4) (2014).

98. *Text Version of OHRP Decision Charts*, U.S. DEP’T OF HEALTH & HUM. SERVS., <http://www.hhs.gov/ohrp/policy/decisioncharttext.html> (last visited Feb. 14, 2015).

99. *See Privacy Settings and Tools*, FACEBOOK, <https://www.facebook.com/settings?tab=privacy> (last visited Feb. 14, 2015).

authorized] representative sufficient opportunity to consider whether or not to participate.”<sup>100</sup> IRBs review the informed consent form to ensure compliance and must continue to review compliance at least once every year.<sup>101</sup>

*c. The Menlo Report*

*The Menlo Report: Ethical Principles Guiding Information and Communication Technology Research* (the “Menlo Report”), funded by the Department of Homeland Security, builds on the Belmont Report and addresses human subjects research in the context of information and communications technology research (“ICTR”).<sup>102</sup> It further builds on the three principles discussed in the Belmont Report, and adds a fourth principle: respect for law and public interest.<sup>103</sup>

The Menlo Report defines a human subject as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) [d]ata through intervention or interaction with the individual, or (2) [i]dentifiable private information.”<sup>104</sup> Intervention is further defined as a physical interaction, but can also be through “manipulations of the subject’s environment that are performed for research purposes.”<sup>105</sup>

The Menlo Report suggests that potential harm as foreseen in the Belmont Report will often be broader in the ICTR context.<sup>106</sup> Here, not only will the subject be at risk, but also individuals beyond that direct research subject, such as friends, family, and other

---

100. 45 C.F.R. § 46.116. The elements of informed consent include: (1) a “statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;” (2) a description of reasonably foreseeable risks; (3) a description of expected benefits; (4) a disclosure of alternative procedures; (5) a description of applicable confidentiality; (6) explanation of compensation for research involving more than minimal risk; (7) a list of relevant people to contact with questions; and (8) a statement that participation in the research is voluntary. *Id.* § 46.116(c)–(d). The regulations define “minimal risk” as a situation in which 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 or psychological examinations or tests.” *Id.* § 46.102(i).

101. Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 235 (2003).

102. *Menlo Report*, *supra* note 11.

103. *Id.*

104. *Id.* at 6 (citing 45 C.F.R. § 46.102(f)).

105. *Id.*

106. *Id.* at 8.



“community relations.”<sup>107</sup> Obtaining informed consent ensures that the Internet user’s individual rights and autonomy are protected.<sup>108</sup>

i. Informed consent in ICTR

In order to ensure all users understand the nature of the terms to which they consent, researchers should draft the language of any information at an eighth-grade level or lower.<sup>109</sup> In some cases, however, informed consent may not be practicable, as with studies concerning “pre-existing public data.”<sup>110</sup> Informed consent may also be waived with certain pre-approved sources of data.<sup>111</sup> These situations generally involve data that has already been placed on the Internet—data for which it would be virtually impossible to obtain informed consent. When a researcher obtains a waiver of the requirement to get informed consent, however, the Menlo Report directs the researcher to inform the subjects of the research after the fact in order to give them the choice to have their data destroyed from the research files.<sup>112</sup> For example, if the researchers in the Facebook study were able to obtain an informed consent waiver under the Common Rule, they would likely still need to obtain informed consent to use the data obtained in the study and destroy files when users did not expressly consent to such use after the fact.

The Menlo Report additionally addresses certain types of invalid informed consent, primarily that which is obtained by coercion or deception.<sup>113</sup> Researchers may not obtain informed consent by suggesting that the subjects will receive improved or enhanced services or that services will be “degraded” or withheld if the subject declines to consent to take part in the research.<sup>114</sup> Also, informed consent for one research purpose will not be valid for any other

---

107. *Id.*

108. See *Applying Ethical Principles to Information and Communication Technology Research: A Companion to the Department of Homeland Security Menlo Report*, U.S. DEP’T OF HOMELAND SEC. 14 (Jan. 3, 2012), <http://www.dhs.gov/sites/default/files/publications/CSD-MenloPrinciplesCOMPANION-20120103-r731.pdf> (“Researchers should be mindful that persons’ dignity, rights and obligations are increasingly integrated with the data and [information and communication technology] systems within which they communicate, transact and in general represent themselves in a cyber context.”).

109. *Menlo Report*, *supra* note 11, at 10.

110. *Id.* at 11.

111. *Id.*

112. *Id.*

113. *Id.* at 10.

114. *Id.*

research purpose other than that for which the particular consent applied.<sup>115</sup> Additionally, as mentioned above, a waiver of informed consent does not relieve the researcher from his or her duty to inform the subject after the fact.<sup>116</sup> When the subject never learns of the research, this is considered deceptive practice.<sup>117</sup>

ii. Respect for law and public interest

The fourth principle added by the Menlo Report for ICTR is respect for law and public interest, which requires compliance with all relevant laws, transparency, and accountability.<sup>118</sup> The Menlo Report defines transparency as “a mechanism to assess and implement accountability, which itself is necessary to ensure that researchers behave responsibly.”<sup>119</sup> Because IRBs have limited information and communications technology (“ICT”) knowledge, they “may not be capable of recognizing that certain ICT research data actually presents greater than minimal risk and may erroneously consider it exempt from review or subject it to expedited review procedures that bypass full committee review.”<sup>120</sup>

The Menlo Report suggests that ICTR should be held to similar standards and oversight as research specifically situated under IRB standards.<sup>121</sup> Currently, researchers in ICT “frequently either do not know of [the IRB review] requirement, or believe that they are not engaged in human subjects research and do not interact with their IRB at all.”<sup>122</sup> It is important to note, however, that the ICTR standards can be seen as a supplement to existing federal privacy laws, which in many cases provide “guidelines and legal mandates about how government agencies can best protect individual privacy.”<sup>123</sup> Where government agencies need “guidance concerning ICTR privacy implications, they should first identify and apply

---

115. *Id.*

116. *Id.* at 11.

117. *Id.*

118. *Id.* at 15.

119. *Id.* at 16.

120. *Id.* at 15.

121. *Id.* at 16–17.

122. *Id.* at 16.

123. *EPIC Comments, supra* note 86.

binding federal privacy laws,” and then adopt the Menlo Report to the extent it does not conflict with federal law.<sup>124</sup>

### *B. Informed Consent Applied*

The Belmont Report and Common Rule serve as a necessary foundation in ensuring the protection of human subjects. However, ascertaining the appropriate level of disclosure and fulfilling these standards proves difficult, especially in areas where the risks of research are unknown.<sup>125</sup>

#### 1. The Purpose of Disclosure

Researchers often find it difficult to disclose the nature of risks involved in a study, given that experiments are inherently uncertain.<sup>126</sup> Uncertainty is a “major barrier to communications between investigators and subjects.”<sup>127</sup> In one common informed consent theory, the most important legal concern about human subjects has been to control the risks presented by research—not to “enable autonomous choice about participation” (the fundamental consideration in establishing informed consent).<sup>128</sup> This suggests that the risks involved must first be outweighed by the research’s social value before informed consent may be addressed.<sup>129</sup> If deemed acceptable, the risks are then relayed to potential subjects as part of the consent process.<sup>130</sup> Though the risks to human subjects often seem to conflict with the pursuit of scientific and social knowledge, “means must be found to ensure that human research subjects will not be manipulated for the sake of knowledge and that their decisions

---

124. *Id.* This Note specifically addresses research standards. Current federal privacy laws must be identified prior to regulatory implementation.

125. Since online human subjects research is in its infancy, the risks involved in testing on subjects are unclear, and thus the level of disclosure necessary to ensure subjects are informed of these risks must be ascertained through further research of the risks imposed on online research subjects.

126. *See* Morin, *supra* note 10, at 189 (“Originally, consent in research was premised on the very notion that makes research distinct, namely the risk of the unknown.”).

127. *Id.* at 213 (discussing Robert J. Levine, *Uncertainty in Clinical Research*, 16 LAW, MED. & HEALTH CARE 174, 174 (1988)).

128. *Id.* at 189; *see also* Belmont Report, 44 Fed. Reg. 23192, 23193–94 (Apr. 18, 1979) (to be codified at 45 C.F.R. pt. 46).

129. Morin, *supra* note 10, at 189.

130. *Id.* at 190.

to participate will be fully voluntary and based on informed and educated consent.”<sup>131</sup>

The need for disclosure involves three considerations: (1) facts that the subjects would generally consider material, (2) information that the researchers consider material, and (3) a description of the purpose for seeking consent.<sup>132</sup> These considerations seem to combine the original disclosure standards relating to treatment with the reasonable volunteer standard applied in experimentation.<sup>133</sup> In new research arenas such as social media and other online resources, it is important that researchers do not forego full disclosure “under the guise of uncertainty, complexity, or pragmatism.”<sup>134</sup> Rather, disclosure should be expanded where research subjects do not readily understand or anticipate potential risks.<sup>135</sup>

## 2. Enforcing Current Regulations

When researchers fail to comply with informed consent standards, subjects have limited remedies. The Common Rule does not create statutory rights, and as such does not provide a private cause of action.<sup>136</sup> Rather, the Common Rule regulations themselves serve as the primary means of enforcing informed consent standards through IRB approval.<sup>137</sup> Compliance is largely monitored through funding agencies that may withhold or refuse to renew funding if the research does not receive IRB approval.<sup>138</sup> Thus, harmed subjects must primarily seek remedies through tort, contract, and privacy laws which require proof of a harm that is often uncertain in the context of online research.<sup>139</sup>

Additionally, the Common Rule serves as the minimum requirement for human subject protection.<sup>140</sup> Some states, therefore,

---

131. *Id.* at 214.

132. *Id.* at 191.

133. *See supra* Section III.A.

134. *See Morin, supra* note 10, at 193.

135. *Id.*

136. Charles Pensabene, Note, *A Canyon Full of Woes: The Havasupai Tribe Illustrates the Need for Cultural Competency in Genetic Research*, 7 ALB. GOV'T L. REV. 637, 641 (2014).

137. *See* 45 C.F.R. §§ 46.108–109 (2014).

138. *See Pensabene, supra* note 136, at 641.

139. *See Fatehi & Hall, supra* note 89, at 620. This article discusses remedies in the context of medical research on human specimens, but these general concepts are still applicable in the behavioral research context. *See Morin, supra* note 10, at 193.

140. Fatehi & Hall, *supra* note 89, at 599.

enforce stricter standards through state and common law.<sup>141</sup> For example, the Maryland Health Code requires IRB approval for all human subjects research, including research that is privately funded.<sup>142</sup> However, absent state-directed action, a private cause of action is still nationally lacking to enforce existing regulation to consistently address research privacy concerns.<sup>143</sup>

#### IV. BRIDGING THE GAP

It is possible that some social media users do not mind taking part in studies, especially if the studies are presented as a condition to continue using the social media websites.<sup>144</sup> However, this willingness to consent may be explained by the fact that most users of social networks do not “reasonably understand the consequences of participation.”<sup>145</sup>

Alternatively, the nature of online privacy expectations may have changed, in that users are more willing to share their private information to the general public.<sup>146</sup> This willingness to publicly “share one’s information . . . can seem incommensurate with the Common Rule.”<sup>147</sup> In discussions regarding change to current informed consent regulation, this cultural change should be considered. However, the nature of privacy expectations in users’ online activities will look different based on the individual website or type of research, and those privacy expectations are far from obsolete. Based on the current state of both IRB standards and Data Use Policies, existing regulation is insufficient to protect against the harms presented by online human subjects research.

##### *A. Implications of Current IRB Regulation*

The above-mentioned cultural shift in privacy expectations looks different across various types of online activity. When someone posts his or her own health information to an online health

---

141. *See id.*

142. MD. CODE ANN., HEALTH-GEN. § 13-2002 (West 2014).

143. *Id.*

144. As the Menlo Report notably suggested though, researchers may not obtain informed consent by suggesting that the subjects will receive improved or enhanced services or that services will be “degraded” or withheld if the subject declines to consent to take part in the research. *Menlo Report*, *supra* note 11, at 10.

145. O’Connor, *supra* note 60, at 479.

146. *See id.*

147. *Id.*

social network, for example, his or her expectation of privacy will be very different compared to “every 14-year old detailing her every thought on a YouTube vlog.”<sup>148</sup> Not only will the latter not necessarily understand the extent to which her information is used for research, she likely would not fathom that such research might attempt to manipulate her very emotions that led to the online behavior in the first place.

Human subjects research may also violate the Child Online Privacy Protection Act (COPPA) by failing to adequately inform younger users (under 13 years old) to the extent necessary to “understand” the terms necessary to obtain sufficient consent.<sup>149</sup> COPPA makes it “unlawful for an operator of a website or online service directed to children, or any operator that has actual knowledge that it is collecting personal information from a child, to collect, use, or disclose the personal identifiable information of a child without obtaining parental consent.”<sup>150</sup> Furthermore, the Common Rule imposes separate standards for research conducted on children.<sup>151</sup> Children may not consent to more than minimal risk, although minimal risk that would otherwise be waivable under Section 46.116 of the Common Rule is still subject to IRB review and the assent of the child.<sup>152</sup> In an experiment such as the Facebook study, Facebook had no way of being certain that it was not studying children. In bypassing IRB review, any unwitting child participant’s consent could have only come from the Facebook Data Use Policy.<sup>153</sup> Since children cannot contract, it seems improbable that the Data Use Policy could be considered sufficient in establishing informed consent.

Additionally, the Facebook study did not concern “pre-existing public data” that researchers analyzed after the subjects had already released information.<sup>154</sup> It does not matter that the data may be subsequently de-identified such that the researchers are unaware of

---

148. *Id.*

149. *See* 16 C.F.R. § 312 (2012).

150. *EPIC Comments, supra* note 86 (quoting 15 U.S.C. § 6502(a)–(b) (2012)).

151. 45 C.F.R. §§ 46.401–.409 (2014). Not every state or agency follows this section of the Common Rule, though.

152. *See* 45 C.F.R. § 46.404 (2009).

153. *See supra* Part I.

154. *Menlo Report, supra* note 11, at 11. This type of data generally applies to previously-collected data for different research than that for which it is currently being used. 45 C.F.R. § 46.101(b)(4) (2014). *See supra* Section III.A.1.b (discussing the Common Rule).

the individual source of each piece of data.<sup>155</sup> This type of research takes a step further in actively creating the data to be researched by intentionally manipulating the user's emotions.<sup>156</sup> Where informed consent is waived up-front, the Menlo Report would require researchers to notify subjects of their involvement in the study and give them the opportunity to "direct the destruction of the data collected about them."<sup>157</sup> In research like the Facebook study, however, the damage is irreversible. The problem exists the moment the researcher changes the way subjects interact with their social media pages, intentionally attempting to change their mood or behavior. This manipulation presents a problem if left unregulated, as this type of massive-scale emotional manipulation could be extremely harmful to an individual's sense of personal autonomy: one of the core values of informed consent.<sup>158</sup>

On the other hand, it is possible that getting permission before every single activity would slow, or even halt, progress and counteract the very purpose of research. "Researchers and those who fund research have a strong interest in minimizing roadblocks to research. Where there are fewer permissions to obtain, research can proceed more quickly and with less cost."<sup>159</sup> This is certainly a valid consideration, as research serves a valuable purpose in our society. It would be difficult to garner large-scale information on human behavior without the types of data aggregation that the Facebook study accomplished.<sup>160</sup> Further, where researchers explicitly and systematically request informed consent, subjects may refuse their consent, effectively distorting the study.<sup>161</sup> However, eliminating these concerns by simply bypassing informed consent requirements altogether creates a scenario that is "frighteningly similar to the very

---

155. *Menlo Report*, *supra* note 11, at 11.

156. *Id.* at 12.

157. *Id.* at 11.

158. Belmont Report, 44 Fed. Reg. 23192, 23193 (Apr. 18, 1979) (to be codified at 45 C.F.R. pt. 46).

159. Fatehi & Hall, *supra* note 89, at 582 (quoting Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119, 137–38 (2009)).

160. Critics of this type of research may argue, however, that controlled small-population studies are just as valuable. The Facebook study was conceivably unnecessary as a matter of behavioral research.

161. Fatehi & Hall, *supra* note 89, at 605.

controversies that gave rise to human subjects research protections in the first place.”<sup>162</sup>

Additionally, because the Common Rule currently lacks a private cause of action, unwitting subjects, such as those in Facebook’s study, must resort to tort, contract, and privacy laws for relief.<sup>163</sup> The harms involved in this type of research, however, are much less obvious when compared to the medical experimentation that generated the Common Rule, and are therefore risky if left unaddressed because their extent is so uncertain.<sup>164</sup> As such, many harmed subjects may be left without a cause of action to repair any damage caused by research like the Facebook study. Since the Common Rule and other regulations guiding human subjects research are meant to provide minimum standards,<sup>165</sup> and the current online privacy regulations inadequately promote and enforce self-regulation, human subjects research regulation must provide a minimum standard for online research that adequately addresses any anticipated risk.

#### *B. Data Use Policies as Continued Bases for Informed Consent*

As noted in Part II, the current default standard for informed consent to online research that is not federally funded, or does not claim FWA, is that of general website Data Use Policies.<sup>166</sup> Information asymmetry<sup>167</sup> gives social media sites like Facebook the opportunity to take advantage of users’ lack of understanding and willingness to assent to the Data Use Policy as a condition to using the site. The principles in the Menlo Report suggest that this type of conditioned consent constitutes involuntary participation, and thus, is not informed consent.<sup>168</sup>

Additionally, the FTC helps to counteract the unfair practices of social media websites that violate the privacy interests of their users.<sup>169</sup> Because the FTC promotes a self-regulatory regime,

---

162. *Id.* at 606.

163. *See id.* at 620.

164. *See supra* Section III.A.1.

165. Fatehi & Hall, *supra* note 89, at 599.

166. *See supra* Part II.

167. Kim, *supra* note 25, at 295.

168. *Menlo Report*, *supra* note 11, at 10.

169. Federal Trade Commission Act, 15 U.S.C. § 45 (2006).



however, there is no mandate that the company comply except where addressed on an individual basis.<sup>170</sup> Further, the actions filed by the FTC against Facebook for violating its own policies exemplifies the failure of this self-regulatory regime.<sup>171</sup> Due to the additional risks involved in behavioral research, the Data Use Policy simply cannot serve as a sufficient basis for informed consent.

### C. Need for Regulatory Reform

Because of these persistent issues combining the lack of IRB regulation of human subjects research through social media and the general lack of oversight in current self-regulatory measures as suggested by the FTC, there exists a need for change in the regulatory regime of online human subjects research. Such change should better protect human subjects, and provide a standard with which to base informed consent in any online study. The solutions attempted by the Menlo Report and the HHS Advance Notice of Proposed Rulemaking exemplify the public awareness of, and concern for, this growing issue. If implemented, a structured legislative approach to the issue will resolve the current lack of consistent oversight that allowed the Facebook study to bypass IRB approval.

## V. SUGGESTED AMENDMENT

When researchers manipulate rather than analyze human behavior, the purpose of the research falls squarely within the principles of the Common Rule.<sup>172</sup> The issue no longer concerns de-identified data, because the study itself seeks to create and manipulate the data it obtains.

In order to resolve this issue, the Common Rule should be expanded to address the particular risks involved in online research, whether or not the research is federally funded. This would necessitate IRB approval<sup>173</sup> for any research beyond simple data

---

170. FTC REPORT, *supra* note 18, at ii.

171. *See supra* Section II.C.

172. *See, e.g.,* O'Connor, *supra* note 60, at 479 (“[D]ata mining of social media content that is performed by Facebook should be subject to the Common Rule. It is, after all, human subjects’ data.”).

173. Based on the fact that research like the Facebook study was conducted for the purposes of furthering the website’s marketability and profitability, Facebook and similar for-profit institutions should not establish their own IRB under these new guidelines. Rather, such research

aggregation. The Common Rule should also provide a private cause of action for parties that are subjects of research that violates Common Rule standards.

Secondly, Data Use Policies should no longer be permitted to serve as the basis for informed consent in research that intends to manipulate human subject behavior, even where the data collected is subsequently de-identified. This will ensure that the clickwrap and browsewrap agreements<sup>174</sup> do not mandate involuntary, and therefore insufficient, consent.

Finally, waiver of the informed consent requirement under Common Rule Section 46.116 should be more strictly implemented, and only waived if there truly is no harm presented by the potential research. In cases where the research aims at manipulating user behavior, such waiver should not apply. Where an IRB determines that waiver is appropriate, however, the researcher should inform the subject after the fact to provide the subject opportunity to direct destruction of the data as recommended by the Menlo Report. Additionally, social media companies should still meet the minimum requirements and suggestions of the FTC report, and follow the guidelines of Do Not Track technology to ensure that users' privacy rights are not violated.

If this suggested amendment had been implemented at the time of the Facebook study, the researchers would not have been able to intentionally manipulate user behavior without first obtaining informed consent in a more direct manner. Thus, such regulation ensures continued protection of online users' privacy rights, and allows users to safely post personal information to online social media pages like Facebook without fear of unknown manipulation.

## VI. CONCLUSION

Human subjects research can, and should, be used to further scientific knowledge and aid social understanding of human behavior. The prevalence of information available online presents immense opportunity that was not in existence when the first ethical

---

should be subject to the approval of an existing non-profit IRB in order to ensure that protection of subjects, rather than competing profit considerations, serves as the main approval factor.

174. *See supra* note 24.

standards were developed.<sup>175</sup> However, as a result of such opportunity, scholars and regulators have raised ethical and regulatory concerns. Without regulatory reform, the Facebook study has opened the door for increased risk of privacy violations that the Common Rule was created to eliminate.<sup>176</sup>

In order to continue online research without violating users' privacy rights, the current regulation should adapt to fit this new research arena. First, the Common Rule should be expanded to apply to online research, whether or not it is federally funded, and additionally incorporate a private cause of action for breach of regulatory standards. Second, data use policies should never form the basis for informed consent in research that manipulates the subjects' behavior. Last, IRB review should involve strict adherence to the Common Rule, and allow waiver of informed consent only where truly appropriate. Thus, in ensuring that informed consent standards are adapted to fit the technological emergence in the research arena, the benefits of research may persist without the negative consequences of using unwilling participants.

---

175. See Mike Schroepfer, *Research at Facebook*, FACEBOOK NEWSROOM (Oct. 2, 2014), <https://newsroom.fb.com/news/2014/10/research-at-facebook/> (“[O]nline services such as Facebook can help us understand more about how the world works.”).

176. See Fatehi & Hall, *supra* note 89, at 606.