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July 17, 2014

Dr. Jerry Menikoff
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Office for Human Research Protections
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Dear Dr. Menikoff:

We are concerned about a recent research project apparently approved by the Cornell Institutional Review Board. The publicly available information about the Cornell IRB's rationale is troubling. Its reasoning, if broadly adopted, would substantially undermine the research ethics protections of the Federal Policy for the Protection of Human Research Subjects (the "Common Rule").[1] We encourage you to investigate the matter, to clarify the record in this case, and to provide suitable guidance on collaborations between institutions that are and are not subject to the Common Rule.

**Background**

The research in question, which we will refer to as "the Facebook Study," is described in a recent article published in the *Proceedings of the National Academy of Sciences* (*PNAS*): "Experimental Evidence of Massive-Scale Emotional Contagion Through Social Networks," by Kramer, Guillory, and Hancock.[2] Investigators "manipulated the extent to which people (N = 689,003) were exposed to emotional expressions in their News Feed."[3] For a one-week period in January 2012, they exposed selected Facebook users to fewer posts containing either positive or negative emotional content. When positive posts were omitted, the users' own posts contained fewer positive words and more negative words, and vice versa when negative posts were omitted. The observed effects were small but noticeable.

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1 *See* 45 C.F.R. pt. 46.

2 Adam D.I. Kramer, Jamie E. Guillory, and Jeffrey T. Hancock, *Experimental Evidence of Massive-Scale Emotional Contagion Through Social Networks*, 111 PROC. NAT'L ACAD. SCI. USA 8788 (2014).

3 *Id.* at 8788.

**Discussion**

There is no serious question that the Facebook Study was "research involving human subjects" as defined in the Common Rule.[4] Investigators manipulated the environment as experienced by Facebook users,[5] obtained data about the users' own posts,[6] and used that data to contribute to generalizable knowledge.[7] There is also no serious question that the Facebook Study was conducted without the "informed consent" of participants as defined in the Common Rule.[8] Facebook users who were involuntarily enrolled in the study were not notified of the study,[9] warned of its risks,[10] provided a point of contact for questions,[11] or given the opportunity to decline participation.[12]

The article's first-named author, Adam D.I. Kramer, was and remains a Facebook employee, a member of its Core Data Science Team.[13] Facebook is a private company; it has not to our knowledge received federal research funding and has not committed to complying with the Common Rule. Facebook has stated publicly that it has an internal review process for research, but has never suggested that this process would meet the Common Rule's standards.[14] A former member of Facebook's Data Science group stated that "there was no internal review board overseeing the studies" at Facebook at the relevant time and that "members of the data science team could run almost any test they wanted, so long as it didn't annoy users."[15]

The article's other two authors, Jamie E. Guillory and Jeffrey T. Hancock, were affiliated with Cornell at the time of the Facebook study.[16] Cornell has entered into a

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4 45 C.F.R. § 46.101(a).

5 *See id.* § 46.102(f).

6 *See id.*

7 *See id.* § 46.102(d).

8 *See id.* §§ 46.116, .117.

9 *See id.* § 46.116(a)(1).

10 *See id.* § 46.116(a)(2).

11 *See id.* § 46.116(a)(7).

12 *See id.* § 46.116(a)(8).

13 *See* Kramer, *supra* note 2, at 8788.

14 *See* Reed Albergotti and Elizabeth Dwoskin, *Facebook Study Sparks Soul-Searching and Ethical Questions*, WALL ST. J., June 30, 2014, http://online.wsj.com/articles/facebook-study-sparks-ethical-questions-1404172292.

15 *Id. See also* Andrew Ledvina, *10 Ways Facebook Is Actually the Devil*, ROKOB (July 4, 2014), http://andrewledvina.com/code/2014/07/04/10-ways-facebook-is-the-devil.html ("While I was at Facebook, there was no institutional review board that scrutinized the decision to run an experiment for internal purposes. Once someone had a result that they decided they wanted to submit for publication to a journal, there definitely was a back and forth with PR and legal over what could be published.")

16 *See Correction*, PROC. NAT'L ACAD. SCI. USA, http://www.pnas.org/content/early/2014/07/03/1412583111.short. The initial published version of the article listed Guillory's affiliation as the Center for Tobacco Control Research and Education at the University of California, San Francisco. Kramer, *supra* note 2, at 8788.

Federalwide Work Agreement promising that it will apply the Common Rule "to all of its human subjects research regardless of the source of support."[17] The Cornell IRB examined the Facebook Study, and concluded that any ethical issues it raised were outside its purview.[18] We believe this conclusion is against the weight of the evidence.

The only official statement of the Cornell IRB's position comes from a press release issued by Cornell's Media Relations Office on June 30:

> Cornell University Professor of Communication and Information Science Jeffrey Hancock and Jamie Guillory, a Cornell doctoral student at the time (now at University of California San Francisco) analyzed results from previously conducted research by Facebook into emotional contagion among its users. Professor Hancock and Dr. Guillory did not participate in data collection and did not have access to user data. Their work was limited to initial discussions, analyzing the research results and working with colleagues from Facebook to prepare the peer-reviewed paper "Experimental Evidence of Massive-Scale Emotional Contagion through Social Networks," published online June 2 in Proceedings of the National Academy of Science-Social Science.
>
> Because the research was conducted independently by Facebook and Professor Hancock had access only to results – and not to any individual, identifiable data at any time – Cornell University's Institutional Review Board concluded that he was not directly engaged in human research and that no review by the Cornell Human Research Protection Program was required.[19]

The statement does not dispute that the Facebook Study was research involving human subjects; it does not argue that informed consent was obtained. Instead, the statement is directed to showing that the Cornell-affiliated investigators did not participate in the portions of the study involving human subjects, so that the Common Rule was not triggered under Cornell's FWA. The statement closely tracks the language of OHRPs nonbinding Guidance on Engagement of Institutions in Human Subjects Research,[20] under which "institutions are considered engaged in … non-exempt human

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17 Cornell University, *Federalwide Assurance (FWA) for the Protection of Human Subjects for Institutions Within the United States*, http://www.irb.cornell.edu/regulations/fwa.htm.

18 *See Media Statement on Cornell University's Role in Facebook 'Emotional Contagion' Research*, CORNELL UNIV. MEDIA RELATIONS OFFICE (June 30, 2014), http://mediarelations.cornell.edu/2014/06/30/media-statement-on-cornell-universitys-role-in-facebook-emotional-contagion-research/. The timing of the review has not been made public and it is not known whether it predated the data collection portion of the Facebook Study.

19 *Id*.

20 Office for Human Research Protections, *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), http://www.hhs.gov/ohrp/policy/engage08.html.

subjects research project … when the involvement of their employees or agents in that project includes"[21] various activities.[22] One of those activities is that investigators "obtain for research purposes identifiable private information,"[23] so the Cornell statement emphasizes that Hancock and Guillory "did not participate in data collection and did not have access to user data"[24] and "had access only to results – and not to any individual, identifiable data at any time."[25]

But this analysis of engagement is incomplete. Obtaining identifiable private information is only one of two ways for an investigator to be engaged in research involving human subjects. The other is to obtain any data, identifiable or not, "through intervention or interaction with [an] individual."[26] The Common Rule defines "intervention" to include "manipulations of the … subject's environment that are performed for research purposes,"[27] precisely what the Facebook Study did by manipulating the contents of users' News Feeds. The Cornell IRB's reasoning, then, is that Guillory and Hancock were not responsible for these manipulations: "Their work was limited to initial discussions, analyzing the research results and working with colleagues from Facebook to prepare the peer-reviewed paper."[28] There are two problems with this reasoning. First, it may significantly understate Guillory and Hancock's participation: the article itself states that all three authors "designed research"[29] Kramer has referred to it as "my and Jamie and Jeff's recent study" and "our research.[30] There are also conflicting reports that the research project may have been initiated by Hancock in a previous grant proposal to the Army Research Office.[31]

Second and more importantly, the Cornell IRB's attempt to place a firewall Cornell investigators and their own study is contrary to both the letter and the spirit of the Common Rule. Consider a hypothetical study: brick manipulation. Researchers at Stoneweall University wish to find out whether people bleed when hit in the head with

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21 *Id.* § III.A

22 *Media Statement*, *supra* note 18. The statement hedges by saying that the Cornell investigators "w[ere] not *directly* engaged in human research." *Id.* (emphasis added). The word "directly" does not not appear either in the Common Rule or in the OHRP Guidance on Engagement.

23 OHRP, *Guidance on Engagement*, *supra* note 20 § III.A.6.

24 *Media Statement*, *supra* note 18.

25 *Id. See also* Kramer, *supra* note 2, at 8789 ("no text was seen by the researchers").

26 45 C.F.R. § 464.102(f)(1).

27 45 C.F.R. § 46.102(f), *See also* OHRP, *Guidance on Engagement,*, *supra* note 20 § III.A.3.

28 *Media Statement*, *supra* note 18.

29 Kramer, *supra* note 2, at 8788. *Cf. Editorial Policies – Journal Policies*, PROC. NAT'L ACAD. SCI. USA, http://www.pnas.org/site/authors/journal.xhtml (defining criteria for authorship of published articles).

30 Post by Adam D.I. Kramer, FACEBOOK (June 29, 2014, 1:05 PM), https://www.facebook.com/akramer/posts/10152987150867796. Kramer referred to "study" and "research," terms that imply a higher degree of participation in the research itself than, e.g., "article."

31 *See* Lorenzo Franceschi-Bicchierai, *The Facebook Manipulation Study's Mysterious Connection to the Military*, MASHABLE (July 2, 2014), http://mashable.com/2014/07/02/facebook-study-military-connection/.

bricks without warning. They design a study, carefully specifying brick size, weight, and velocity. Then they recruit a colleague at Brickbook, which throws bricks at people. The Brickbook-affiliated researcher reports back on the brick-induced bleeding (carefully withholding any identifiable private information about subjects) and the researchers collectively draft a paper. The reasoning used by the Cornell IRB here would allow the Stonewall IRB to conclude that the brick manipulation study was "conducted independently by Brickbook" and that Stonewall affiliates' "work was limited to initial discussions and analyzing the research results." By delegating the implementation of the study to Brickbook, the Stonewall investigators have successfully routed around their own IRB. Literally any research project, no matter how ethically troubling, could be outsourced to an institution with no ethical review process—Stonewall's FWA notwithstanding.

Additional reports suggest that the Cornell IRB may have had different and in some respects inconsistent bases for its decision. Susan Fiske, the article's editor at *PNAS*, wrote in an email to a reporter:

> I was concerned about this ethical issue as well, but the authors indicated that their university IRB had approved the study, on the grounds that Facebook filters user news feeds all the time, per the user agreement. Thus, it fits everyday experiences for users, even if they do not often consider the nature of Facebook's systematic interventions. The Cornell IRB considered it a pre-existing dataset because Facebook continually creates these interventions, as allowed by the user agreement.[32]

This brief passage gives three distinct rationalizations of the Facebook Study: (1) Participants gave *consent* for the study's filtering "per the user agreement." (2) The study posed *minimal risk* to participants because "it fit[] everyday experiences." (3) The study involved only *pre-existing data* "because Facebook continually creates these interventions." Each of these rationalizations appeals to a different exception to the Common Rule's informed consent requirement. Each would have been unnecessary if the Facebook study had truly been "conducted independently by Facebook." And each is unconvincing.

*Implicit Consent*. The theory that users consented to the study simply by using Facebook confuses the thin and formalistic "consent" required to make terms of service legally binding[33] with the thick and meaningful *informed* consent required under the

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[32] *See* E-mail from Susan Fiske to Matt Pearce, https://twitter.com/mattdpearce/status/483398731731976192. This is a third-hand report of the IRB's reasoning, so it may not be entirely accurate. One of the reasons an OHRP investigation would be valuable is simply to clear the air, given the numerous and conflicting explanations of the Cornell IRB's reasoning that have been offered in this high-profile incident. Other IRBs will make their decisions in future cases in part based on their understanding of how the Cornell IRB acted here.

[33] For strong critiques of this approach to contractual consent, see NANCY S. KIM, WRAP CONTRACTS: FOUNDATIONS AND RAMIFICATIONS (2013); MARGARET JANE RADIN, THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW (2012); Mark A. Lemley, *Terms of Use*, 91 MINN. L. REV. 459 (2006).

Common rule. The article is simply wrong when it states, "[The study] was consistent with Facebook's Data Use Policy, to which all users agree prior to creating an account on Facebook, *constituting informed consent for this research*."[34] The version of the Data Use Policy in force in January 2012 did not include the word "research," let alone an explanation of the Facebook study's purpose and methods.[35] It said nothing about risks or discomforts, gave no contact information, and offered no opt-out from the study. Many Facebook users have never read the Data Use Policy. In addition, Facebook has acknowledged that it did not exclude minors from the study.[36] For the same reasons given above, the Data Use Policy does not constitute the "assent" required of minor participants,[37] nor did Facebook attempt to obtain the required "permission" from their parents.[38]

*Minimal Risk*. The argument that the Facebook Study "fits everyday experiences for users" is an apparent reference to the Common Rule's standard for waiving informed consent when "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."[39] It is unclear whether the Facebook Study really did involve minimal risk under this definition. It is unclear whether the Cornell IRB documented the study's eligibility for a

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34 Kramer, *supra* note 2, at 8789 (emphasis added).

35 *See Facebook Data Use Policy*, FACEBOOK (revised Sept. 23, 2011), *available at* http://thecoudrain.com/files/documents/Facebook-Data-Use-Policy.pdf. The only remotely relevant portion of the Data Use Policy read:

> **How we use the information we receive**
>
> We use the information we receive about you in connection with the services and features we provide to you and other users like your friends, the advertisers that purchase ads on the site, and the developers that build the games, applications, and websites you use. For example, we may use the information we receive about you:
>
> - as part of our efforts to keep Facebook safe and secure;
> - to provide you with location features and services, like telling you and your friends when something is going on nearby;
> - to measure or understand the effectiveness of ads you and others see;
> - to make suggestions to you and other users on Facebook, such as: suggesting that your friend use our contact importer because you found friends using it, suggesting that another user add you as a friend because the user imported the same email address as you did, or suggesting that your friend tag you in a picture they have uploaded with you in it.
>
> Granting us this permission not only allows us to provide Facebook as it exists today, but it also allows us to provide you with innovative features and services we develop in the future that use the information we receive about you in new ways.

36 *See* Reed Albergotti and Elizabeth Dwoskin, *supra* note 14.

37 *See* 45 C.F.R. §§ 46.404–.408(requiring "assent" of minor participants under most circumstances), .402(b) (defining "assent").

38 *See id*. § 46.404–.408 (requiring "permission" of parents under most circumstances), .402(c) (defining "permission").

39 *Id.* § 46.102(i).

waiver, as it would have had to do to grant one.[40] But it is clear that the Facebook Study qualified at most for an alteration of informed consent, not a complete waiver.[41] The study could have practicably been carried out by showing Facebook users selected for the experiment a notice in general terms that their News Feed content might be selectively excluded, and providing them a point of contact and an opportunity to avoid participation.[42] Similarly, a standardized debriefing could easily have been given via email or private Facebook message to the users who were unwittingly drafted into the study.[43]

*Pre-Existing Data*. Finally, the treatment of the study as retrospective rather than prospective fundamentally mischaracterizes it. It is true only in a general sense that "Facebook continually creates these interventions." A surgeon "continually creates … interventions," but knowledge of this general fact does not constitute informed consent to any specific surgical procedure. So here. The specific intervention at issue—the selective hiding of emotionally laden posts—was imposed on users by the Facebook Study investigators as part of their research program. Thus it is completely misleading to describe the Facebook Study dataset as "pre-existing." It came into existence in January 2012 precisely as a result of a manipulation designed by the Cornell investigators. To treat the dataset as pre-existing effaces their role in creating it through intervention with human subjects.

The confluence of these three weak explanations for noncompliance with the Common Rule is cause for concern. If Fiske's account of the Cornell IRB's reasoning is accurate, it suggests an attempt to cobble together a novel theory of Common Rule compliance from the scraps of three failed attempts. Together, they add up to a theory not of Common Rule compliance but of Common Rule evasion.

**OHRP's Role**

We encourage OHRP to undertake a full investigation into the Cornell IRB's treatment of the Facebook Study in light of Cornell's obligations under its FWA. Among the questions such an investigation should consider are:

- When was the Facebook Study presented to the Cornell IRB for approval?
- What information about the Facebook Study's research protocols was provided to the Cornell IRB?
- What roles did Cornell affiliates play in the Facebook Study?
- What were the funding sources, if any, for the Facebook Study?

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40 *Id.* § 46.116(d).

41 *Id.*

42 *See id.* § 46.116(d)(3).

43 *See id.* § 46.116(d)(4).

- What similar "interventions" does Facebook "continually create," and how are those interventions reviewed, by Facebook and by institutions operating under FWAs?
- Does the Cornell IRB have a consistent practice for reviewing proposed research involving collaborations with institutions not operating under an FWA?
- What were the Cornell IRB's conclusions and reasoning?
- Does the Cornell IRB have a practice of approving proposed research in which a third party will obtain data using interventions designed in whole or in part by Cornell affiliates?
- Does the Cornell IRB have a practice of relying on website terms of service or other mass-market form contracts as constituting informed consent?
- Does the Cornell IRB have a practice of treating attempts to influence the emotional state of research subjects as posing "minimal risk?"
- Does the Cornell IRB have a consistent working definition of pre-existing data?

We also encourage OHRP to use this occasion to issue guidance clarifying institutional responsibility in similar situations when they arise in the future. Among the issues on which OHRP could usefully provide guidance are:

- The division of Common Rule responsibility when one institution engaged in collaborative research is covered by an FWA and another is not.
- Best practices for institutions not covered by an FWA when they engage in research that may or may not be covered by another institution's FWA.
- The degree to which an institution's employees and agents may participate in research design, for purposes of defining when they are "engaged" in research.
- Under what circumstances one institution or person acts as the "agent" of another, for purposes of defining when the latter is "engaged" in research.
- The conditions, if there are any, under which website terms of service or other mass-market form contracts can suffice to provide informed consent.

We thank you for your interest in this matter.

Sincerely,

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Encl:

Letter to Federal Trade Commission
Letter to *Proceedings of the National Academy of Sciences of the U.S.A.*