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Inder M. Verma
Editor-in-Chief, *Proceedings of the National Academy of Sciences of the U.S.A.*
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Verma:

We are concerned about 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 (the Kramer Article).¹ It reports on an experiment that “manipulated the extent to which people (N = 689,003) were exposed to emotional expressions in their News Feed” (the Facebook Study).² For a one-week period in January 2012, selected Facebook users in the experimental groups were exposed to fewer posts containing either positive or negative 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.

The sticking point is that Facebook users were involuntarily enrolled in the Facebook Study. They were not notified of their participation (and have not been to this day); they were not given the opportunity to remove themselves from the experiment. You have written that the research behind the article “may have involved practices that were not fully consistent with the principles of obtaining informed consent.”³ This is a serious understatement. The Facebook Study violated broadly accepted norms of research ethics. Its publication violated *PNAS*’s stated editorial policies. Retraction is the only appropriate response.

¹ 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), <http://www.pnas.org/content/111/24/8788.full.html>.

² *Id.* at 8788.

³ Inder M. Verma, *Editorial Expression of Concern*, PROC. NAT’L ACAD. SCI. USA (July 3, 2014) <http://www.pnas.org/cgi/doi/10.1073/pnas.1412469111>.

The Common Rule

We would like to start with the principal federal regulation governing human subjects research, the Federal Policy for the Protection of Human Research Subjects, better known as the “Common Rule.”⁴ It provides a widely accepted ethical floor for human subjects research. Adherence to the Common Rule is a legal requirement for all research funded by fifteen federal agencies,⁵ and “[a]dherence to the Common Rule is PNAS policy.”⁶

In brief, the Common Rule applies to all “research involving human subjects” that is funded by the relevant agencies.⁷ Substantively, it requires detailed informed consent from research participants, subject to two important exceptions.⁸ First, participants are not considered “human subjects” at all if investigators study them only by examining non-private pre-existing data;⁹ and second, informed consent can be waived or altered for research projects involving “minimal risk.”¹⁰ Procedurally, the Common Rule requires each funded institution to have an institutional review board (IRB) that examines research projects to ensure compliance with the substantive informed consent rules.¹¹

At the outset, the Facebook Study is clearly “research involving human subjects” under the Common Rule. First, the Common Rule defines “research”:

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. ...¹²

The Facebook Study systematically examined “verbal expressions on Facebook”¹³ to develop “experimental evidence to support the controversial claims that emotions can spread throughout a network,”¹⁴ and thus unquestionably qualifies as “research.” The Facebook Study also involved “human subjects” as understood by the Common Rule:

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

⁴ 45 C.F.R. pt. 46. This is technically only the Department of Health and Human Services’ adoption of the Common Rule. Other federal agencies have also adopted it, *see, e.g.*, 32 C.F.R. pt. 219 (Department of Defense), but in each case using identical text, hence the name “Common” Rule.

⁵ *See* 45 C.F.R. § 46.101(a).

⁶ Verma, *supra* note 3

⁷ 45 C.F.R. § 46.101(a).

⁸ *See id.* §§ 46.109(b) (requiring review for informed consent), 46.116 (describing informed consent), 46.117 (requiring documentation of informed consent).

⁹ *See id.* § 46.102(f).

¹⁰ *See id.* § 46.116(d).

¹¹ *See id.* §§ 46.107–.115.

¹² *Id.* § 46.102(d).

¹³ Kramer, *supra* note 1, at. 8789.

¹⁴ *Id.*

(1) Data through intervention or interaction with the individual, or (2) Identifiable private information.¹⁵

The Facebook Study meets every element of this definition. Facebook users are “living individual[s],” the authors of the Facebook Study are “investigators,” and they obtained “data” “about” those users, in the form of statistical information about the emotional content of the users’ posts. Thus, the only remaining question is whether the data was obtained “through intervention or interaction with the individual.” The Common Rule defines “intervention” to include “manipulations of the subject or the subject’s environment that are performed for research purposes.”¹⁶ As the Kramer Article itself states, “The experiment *manipulated* the extent to which people (N = 689,003) were exposed to emotional expressions in their News Feed.”¹⁷ Specifically, the Facebook Study “omitted”¹⁸ posts with positive or negative emotional content from subjects’ News Feeds and observed the resulting effects.

Informed Consent

The Facebook Study should have obtained the informed consent of participants. The Common Rule’s definition of “informed consent,” includes, at a minimum, providing a description of the research to participants,¹⁹ disclosing “any reasonably foreseeable risks or discomforts,”²⁰ providing a point of contact for questions,²¹ and giving participants the ability to opt out with “no penalty or loss of benefits to which the subject is otherwise entitled.”²² Formally, informed consent must be documented using a signed form, a copy of which is given to the participant.²³ The *PNAS* editorial policies adopt these requirements, stating, “For experiments involving human participants, authors must also

¹⁵ 45 C.F.R. § 46.102(f).

¹⁶ *Id.*

¹⁷ Kramer, *supra* note 1, at 8788 (emphasis added).

¹⁸ *Id.*

¹⁹ 45 C.F.R. § 46.116(a)(1).

²⁰ *Id.* § 46.116(a)(2).

²¹ *Id.* § 46.116(a)(7).

²² *Id.* § 46.116(a)(8).

²³ *Id.* § 46.117(a).

include a statement confirming that informed consent was obtained from all participants.”²⁴

The Facebook study did none of this. Participants were not told (and have not been told) that they were part of a study: no one gave them a point of contact for questions or offered them the ability to opt out. No one obtained specific consent for the study, let alone signed forms. Most of all, it was reasonably foreseeable that the Facebook Study would cause discomfort to participants. The study was designed to demonstrate that “emotions expressed by friends, via online social networks, influence our own moods,”²⁵ and the initial hypothesis was that participants in one of the treatment groups would “express increased negativity.”²⁶ It was also arguably reasonably foreseeable given the design of the study that some participants might experience risk of more significant psychological harms from the weeklong suppression of positive emotional content in a News Feed participants had been led to believe was representative of their friends’ posts.

The only text relating to participant consent in the Kramer Article read:

[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.²⁷

But Facebook’s Data Use Policy did not even remotely constitute “informed consent” under the Common Rule standard. 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

²⁴ See *Editorial Policies - Journal Policies*, PROC. NAT’L ACAD. SCI. USA, <http://www.pnas.org/site/authors/journal.xhtml>. The policies refer to “experiments” rather than to “research,” but there is no serious question that the Facebook Study was an “experiment.” The first words of the Kramer Article’s title are “Experimental evidence” and it repeatedly refers to the Facebook Study as an “experiment” or “experiments.” See Kramer, *supra* note 1, *passim* (“In an *experiment* with people who use Facebook ... The *experiment* manipulated the extent to which people (N = 689,003) were exposed to emotional expressions in their News Feed. ... People who viewed Facebook in English were qualified for selection into the *experiment*. Two parallel *experiments* were conducted for positive and negative emotion ... Both *experiments* had a control condition ... The *experiments* took place for 1 wk ... For each *experiment* ... After establishing that our experimental groups did not differ in emotional expression during the week before the *experiment* ...” (emphasis added)). Technically, the policies state that the published article must “include a statement” that informed consent was obtained, rather than stating that informed consent must actually have been obtained. The Kramer Article did include such a statement, but as described below, that statement was false on its face in a way that should have been evident to the editorial staff of PNAS.

²⁵ Kramer, *supra* note 1, at 8789.

²⁶ *Id.*

²⁷ *Id.*

purpose and methods.²⁸ It said nothing about risks or discomforts, gave no contact information, and offered no opt-out from the study. Whether or not the Data Use Policy was legally effective to allow Facebook access to users' personal information, it simply did not provide users with any of the information that would have made their consent "informed."

In addition, Facebook has acknowledged that it did not exclude minors from the study.²⁹ The Common Rule generally requires that in research involving minors "adequate provisions are made for soliciting the assent of the children."³⁰ The standard for "assent" requires "a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent."³¹ For the same reasons given above, the Data Use Policy does not constitute "assent" from minor participants in the Facebook Study. In addition, the Common Rule requires "adequate provisions ... for soliciting ... the permission of [the children's] parents or guardians."³² Facebook made no attempt whatsoever to notify the parents of minor participants, let alone to obtain their agreement.

Some observers have argued that the Facebook Study involved "minimal risk" to participants and thus it could have been conducted without obtaining full informed

²⁸ 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.

²⁹ 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>.

³⁰ 45 C.F.R. § 46.404.

³¹ *Id.* § 46.402(b).

³² *Id.* § 46.404; see also *id.* § 46.402(c) (defining "permission").

consent.³³ There are three serious problems with using this argument as a retroactive justification. First, whether or not the study involved minimal risk is debatable; no one connected with the Study or with *PNAS* has addressed the issue in any detail.³⁴ Second, the Common Rule permits the “waiver” or “alteration” of informed consent only when an “IRB finds and documents” a number of threshold conditions.³⁵ But as discussed below, no IRB reviewed the substance of the Facebook Study, let alone made the requisite findings. And third, the Facebook Study fails at least two of those threshold conditions. One is that the “research could not practicably be carried out without the waiver or alteration.”³⁶ While full informed consent might arguably have biased the results of the Facebook Study, it could practicably have been carried out with only an alteration rather than a full waiver.³⁷ For example, participants could have been informed of a research project involving selective exclusion of News Feed Content in general terms and provided with a point of contact and opportunity to avoid participation. The Common Rule does not countenance omitting informed consent entirely in these circumstances. Another threshold condition is, “Whenever appropriate, the subjects will be provided with additional pertinent information after participation.”³⁸ Here, it would have been easy to provide a standard debriefing (e.g. through an email or Facebook private message) to participants after the study concluded.

To summarize: the Facebook Study was human subjects research, and it was carried out without the informed consent of participants. Insofar as *PNAS* requires that the studies it publishes adhere to the Common Rule, *PNAS* should not have published the Kramer Article, and should immediately retract it.

IRB Review

The Common Rule requires that each institution receiving federal research funding have an IRB that meets stringent requirements on its composition, powers, duties,

³³ See, e.g., Michelle N. Meyer, *How an IRB Could Have Legitimately Approved the Facebook Experiment—and Why that May Be a Good Thing*, THE FACULTY LOUNGE (June 29, 2014), <http://www.thefacultylounge.org/2014/06/how-an-irb-could-have-legitimately-approved-the-facebook-experimentand-why-that-may-be-a-good-thing.html>.

³⁴ See generally 45 C.F.R. § 46.102(i) (defining “minimal risk”).

³⁵ 45 C.F.R. § 46.116(d).

³⁶ *Id.* § 46.116(d)(3).

³⁷ See Meyer, *supra* note 33.

³⁸ 45 C.F.R. § 46.116(d)(4).

procedures, and record-keeping.³⁹ All covered human subjects research must be approved by the institution's IRB.⁴⁰ The *PNAS* editorial policies explicitly adopt this requirement, stating, "Research involving Human and Animal Participants and Clinical Trials must have been approved by the author's institutional review board."⁴¹ At the time of the Facebook Study, the Kramer Article's authors were affiliated either with Facebook (Kramer), or with Cornell (Guillory and Hancock).⁴² At neither institution did an IRB approve the Facebook Study.

There is no suggestion that Facebook has an IRB meeting the stringent requirements of the Common Rule, let alone one that approved the Facebook Study. Facebook is a private company; it has not to our knowledge received federal research funding and thus does not have a Federalwide Work Agreement in place with the federal government certifying that it has an IRB. The Kramer Article's editor at *PNAS*, Susan Fiske, has stated, "[Facebook] seems to have reviewed [the Facebook Study] as well in some unspecified way,"⁴³ indicating that she does not regard Facebook's "unspecified" process as equivalent to IRB review. Kramer similarly describes the Facebook process only as "our internal review practices."⁴⁴ 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."⁴⁵

Cornell does have an IRB, which "concluded that ... no review by the Cornell Human Research Protection Program was required."⁴⁶ But this was not a decision that the

³⁹ See *id.* §§ 46.107 (requiring IRB to comprise at least five members of specified backgrounds, competencies, and affiliations), .108 (requiring written procedures and operation by quorum at convened meetings), .109 (detailing substance of IRB duties and authority), .110 (allowing expedited review of certain types of cases), .111 (listing requirements that IRB "shall determine ... are satisfied" by any approved project), .112 (limiting scope of institutional review of IRB decisions), .113 (requiring IRB to have authority to terminate non-compliant research), .114 (describing IRB responsibilities in cases involving multiple institutions), .115 (describing required IRB record-keeping).

⁴⁰ See *id.* § 46.109(a).

⁴¹ *Editorial Policies*, *supra* note 24. The *PNAS* Policies also state, "Authors must include in the Methods section a brief statement identifying the institutional and/or licensing committee approving the experiments." *Id.* The Kramer Article does not contain any subsections, let alone one designated as "Methods." Nor does it mention any "institutional and/or licensing committee."

⁴² See *Correction*, PROC. NAT'L ACAD. SCI. USA, <http://www.pnas.org/content/early/2014/07/03/1412583111.short>.

⁴³ E-mail from Susan Fiske to Adrienne LaFrance (June 29, 2014, 9:24 PM), <https://twitter.com/AdrienneLaF/status/483429026984247297/photo/1>.

⁴⁴ Post by Adam D.I. Kramer, FACEBOOK (June 29, 2014, 1:05 PM), <https://www.facebook.com/akramer/posts/10152987150867796>.

⁴⁵ Albergotti and Dwoskin, *supra* note 29.

⁴⁶ *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/>.

Facebook Study was in compliance with the Common Rule; it was a decision that *Cornell* was in compliance with the Common Rule. The difference is significant. The Common Rule applies as law only to research with a nexus to federal funding.⁴⁷ Although the Facebook Study was not itself federally funded,⁴⁸ Cornell has committed to the federal government that it will apply the Common Rule “to all of its human subjects research regardless of the source of support.”⁴⁹ Thus, the legal threshold triggering Common Rule obligations is when Cornell is “engaged in research which is covered by [the Common Rule].”⁵⁰ The key word here is “engaged.”⁵¹ If Cornell investigators are not “engaged” in human subjects research, it could be for two reasons. The research itself might not be human subjects research, or it might not be Cornell investigators who are engaged in it.

The Cornell IRB took the latter approach: it concluded only that Cornell investigators did not participate in the human subjects research portions of the Facebook Study. It stated that Hancock and Guillory “analyzed results from previously conducted research by Facebook” and “did not participate in data collection and did not have access to user data.”⁵² Indeed, the Cornell IRB confirmed that its approval did not extend to the study as a whole when it stated that the Facebook Study was “research . . . conducted independently by Facebook,”⁵³ Cornell did not bless the research; Cornell washed its hands of it.

Thus, *PNAS* should not have relied on the Cornell IRB’s limited review. The purpose of the *PNAS* editorial policies on informed consent and IRB review is to ensure that published research was conducted ethically. The Common Rule is a legal implementation of an ethical standard, not the ethical standard itself. The federal government has chosen only to regulate research at federally funded institutions; there is no reason for *PNAS* to insist on ethical research only at federally funded institutions. Put another way, the *PNAS* decision to rely on Cornell’s IRB review mistook a *jurisdictional* limit on the Common Rule’s applicability for a *substantive* one.

This is why the argument that the Facebook Study involved only a “pre-existing dataset” misses the point.⁵⁴ The theory of pre-existing datasets is that an investigator who does not engage in “intervention or interaction” with a human subject—i.e. one who works only with data that already exists—can harm a subject only indirectly, through misuse of that data. The Common Rule therefore focuses on privacy protections for such

⁴⁷ 45 C.F.R. § 46.101.

⁴⁸ *Media Statement*, *supra* note 46.

⁴⁹ 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>

⁵⁰ 45 C.F.R. § 46.103(a).

⁵¹ See generally 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>.

⁵² *Media Statement*, *supra* note 46.

⁵³ *Id.*

⁵⁴ See, e.g., E-mail from Susan Fiske, *supra* note 43.

subjects, and draws a bright line at the use of “[i]dentifiable private information.”⁵⁵ Thus, the Kramer Article notes that “no text was seen by the researchers,”⁵⁶ and the Cornell IRB reasoned that since Hancock “had access only to results—and not to any individual, identifiable data at any time ... he was not directly engaged in human research.”⁵⁷

There are two problems with this reasoning. First, even if the Facebook Study dataset had been “pre-existing” as to *Cornell*, it was not pre-existing as to *Facebook*. Kramer and colleagues at Facebook engaged in “intervention” as described above, and therefore it is irrelevant whether they also obtained “identifiable private information.” They were already engaged in human subjects research as defined by the Common Rule.⁵⁸ Second, the Facebook Study dataset was not even pre-existing as to Cornell. The Kramer Article itself states that Hancock and Guillory “designed [the] research,”⁵⁹ and Cornell has confirmed that they were involved in “initial discussions” as well as data analysis.⁶⁰ These facts call into question the Cornell IRB’s characterization of the Facebook Study as “research ... conducted *independently* by Facebook.”⁶¹

Another version of this argument is that Facebook already manipulates News Feed content extensively and thus the results of those manipulations are pre-existing data.⁶² Whether one agrees with the premise of this argument, the conclusion is a *non sequitur*. The Facebook Study dataset came into existence in January 2012 precisely as a result of the manipulation “designed” and “performed” by the authors of the Kramer Article. Facebook may manipulate users regularly, but this specific manipulation was still the product of investigator intervention.

To summarize: the Facebook Study was human subjects research, and it was never substantively approved by an IRB. Insofar as *PNAS* requires that the studies it publishes be approved by IRBs, *PNAS* should not have published the Kramer Article, and should immediately retract it.

IRB Laundering

The Facebook Study illustrates the ethical issues that can arise with multi-institution research. In particular, it illustrates the danger of IRB laundering, in which “academic researchers evade formal ethics-review processes by collaborating with corporate

⁵⁵ 45 C.F.R. § 46.102(f)(2).

⁵⁶ Kramer, *supra* note 1, at 8789.

⁵⁷ *Media Statement*, *supra* note 46.

⁵⁸ See 45 C.F.R. § 46.102(f)(1).

⁵⁹ Kramer, *supra* note 1, at 8788.

⁶⁰ *Media Statement*, *supra* note 46. See also H. Roger Segelken and Stacey Shackford, *News Feed: ‘Emotional Contagion’ Sweeps Facebook*, CORNELL CHRON. (June 10, 2014) (describing generically the work of “researchers” in the Facebook Study and attributing prominent role to Cornell-affiliated investigator).

⁶¹ *Id.* (emphasis added).

⁶² See E-mail from Susan Fiske to Matt Pearce, <https://twitter.com/mattdpearce/status/483398731731976192>.

researchers who do experiments and collect data within a company where ethics review processes are looser.”⁶³ The Kramer Article’s authors may well have acted in good faith, but unscrupulous investigators could exploit the precedent set by its publication.

Consider a hypothetical study: brick manipulation. Researchers at Stonewall University wish to find out whether people bleed when hit in the head with bricks. 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.

Fortunately, the brick manipulation study is entirely hypothetical. But the rationalizations offered by *PNAS* in defense of the Kramer Article would also allow it to publish the brick manipulation paper. The Stonewall IRB could conclude the research was “conducted independently by Brickbook” and that Stonewall affiliates’ “work was limited to initial discussions and analyzing the research results.” As a private company, Brickbook has no IRB, indeed no ethics review process of any sort; Stonewall has an IRB but not one that considers the ethics of work carried out at Brickbook. The same reasoning that led *PNAS* to publish the Kramer Article would say that the blatantly unethical brick manipulation paper is also suitable for publication. 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 smuggled through an institution with no ethical review process.

The reverse is true as well: unregulated institutions could launder unethical projects by giving them a nominal connection to an IRB-regulated institution. Suppose that Brickbook has been hitting people with bricks as part of its day-to-day business. Eager to prove that brick manipulation is harmless, Brickbook hits some people with cinder blocks instead and observes the aftermath. To turn this project into a publishable paper, the Brickbook research team approaches an investigator from Stonewall. Once again, the Stonewall IRB could reasonably conclude that the research was “conducted independently by Brickbook.” Once again, the *PNAS* policy of treating the study as “approved” by an IRB would be badly mistaken.

Fortunately, the Common Rule already illustrates how this gap can be plugged. *PNAS* and other journals cannot just defer to the *letter* of the Common Rule, because the Common Rule does not attempt to reach many non-federally funded projects. But *PNAS* can embrace the *spirit* of the Common Rule’s treatment of multi-institution research. When “cooperative research” is federally funded, the Common Rule states that “*each*

⁶³ Ed Felten, *Facebook’s Emotional Manipulation Study: When Ethical Worlds Collide*, FREEDOM TO TINKER (June 30, 2014), <https://freedom-to-tinker.com/blog/felten/facebooks-emotional-manipulation-study-when-ethical-worlds-collide/>.

institution is responsible for safeguarding the rights and welfare of human subjects.”⁶⁴ The Office for Human Research Protections treats grant-receiving institutions as “engaged” in human subjects research even when some other institution carries out the interventions and data collection.⁶⁵ OHRP also has guidance on coordination between multiple IRBs in cooperative research projects.⁶⁶

Thus, in addition to retracting the Kramer Article, *PNAS* should make explicit the broader policy at work. In the future, when considering articles describing human subjects research, *PNAS* should apply the Common Rule not simply as written, but *as though all the research described in the articles had been directly federally funded*. Thus, IRB approval must cover the entire research project described in an article.

Conclusion

Internet companies are amassing huge volumes of data on their users. Scientists are understandably eager to mine that data for scientific insights, and to use their expertise to help companies ask better questions. These collaborations can enrich public understanding in ways we are only beginning to fathom.

But the interface between research and practice is also a boundary between two institutional cultures. In one of them—academic science—we have had decades of careful conversations on appropriate ethical and regulatory principles.⁶⁷ The Common Rule is not just a legal requirement; it is also the embodiment of a collective commitment to human dignity, informed consent, and research integrity. The other culture—corporate analytics—is currently almost entirely unregulated. But this is not the result of a conscious societal decision that ethical principles do not apply there, or that legal oversight would be inappropriate. Instead, the corporate culture of giant data storehouses and constant A/B testing simply grew up, at first slowly and then quickly.

The Facebook Study offers us a moment for reflection, a chance to discuss the ethical precepts that apply to the practice of corporate data gathering—and to decide how it should be regulated. It is unlikely that the right answer is to copy over the existing Common Rule framework of IRB review in every last detail. It is also unlikely that the right answer is to leave this practice entirely alone, to say that it is simply a research ethics free-fire zone. The approach that *PNAS* took towards the Kramer Article, unfortunately, captured the worst of both wrong answers: a formalistic checklist for IRB review that entirely bypassed the underlying ethical concerns.

⁶⁴ 45 C.F.R. § 46.114 (emphasis added).

⁶⁵ See *Guidance on Engagement*, *supra* note 51, § III.A.1.

⁶⁶ See *id.* § IV.

⁶⁷ See generally NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979).

In the short term, *PNAS* needs to set its house in order by retracting the Kramer Article and reiterating its commitment to the substance—rather than the form—of Common Rule compliance. In the longer term, we hope that *PNAS* will use this occasion to start a dialogue on appropriate research ethics for Internet data projects, and seek to promote this valuable research within a framework of trust, dignity, accountability, and integrity.

Sincerely,

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Encl:

Letter to Federal Trade Commission
Letter to Office for Human Research Protections

* Affiliations listed for identification purposes only.