Fall 2014

Heterogeneity in IRB Policies with Regard to Disclosures About Payment for Participation in Recruitment Materials

Christopher Robertson
Boston University School of Law

Megan Wright

Arizona Legal Studies
Discussion Paper No. 14-32

Heterogeneity in IRB Policies with Regard to Disclosures about Payment for Participation in Recruitment Materials

Megan S. Wright
Yale Law School

Christopher T. Robertson
The University of Arizona
James E. Rogers College of Law

November 2014

Heterogeneity in IRB Policies with Regard to Disclosures about Payment for Participation in Recruitment Materials

Megan S. Wright and Christopher T. Robertson

Introduction

The payment of human subjects is an area where Institutional Review Boards (IRBs) have wide discretion. Although the "Common Rule"[1] requires the provision of full information to human research participants to secure valid consent, the Rule is silent on the issue of payment.[2] Still, some federal agencies offer guidance on the matter. For example, the National Science Foundation (NSF) cautions that high payments for risky research "may induce a needy participant to take a risk that they normally would prefer not to take."[3] For research under its purview, the Food and Drug Administration (FDA) guidance provides that "[a]dvertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type."[4] One might read the FDA guidance to permit the advertisement for human subjects to state the specific amount of payment, as long as it is not emphasized.

While there is a larger debate about whether and how human subjects should be paid, we focus on the permissibility of investigators advertising the *amount* of compensation that they intend to pay human subjects. Can a pre-recruitment postcard offer a patient $50 to complete a survey? May a sign on a public bus mention that the study will pay up to $2,500? Potential research participants must decide whether to answer the phone or whether to show up at a screening site, and they may utilize such payment information to inform those decisions. These preliminary decisions are made prior to the formal consent stage of research, where complete information about risks and benefits is provided.

For both practical and ethical reasons, recruitment is a sensitive stage of research. In practical terms, the initial solicitations are important for recruiting an appropriate and unbiased sample, without excessive delay.[5] On the other hand, IRBs may seek to regulate disclosure about payment to protect human subjects from being unduly influenced by money, which may prevent them from fairly evaluating the risks of participation.[6] On this view, people might actually make better initial decisions about whether to pursue a research opportunity if they were blinded to payment information. Nonetheless, such a ban runs against the grain of other bioethical imperatives for informed decision making.[7]

In this sensitive domain, it is unknown how IRBs have responded to the discretion allowed by the Common Rule and the guidance given by the FDA. In particular, have IRBs developed policies about whether researchers are allowed to provide precise payment information for study participation in recruitment materials? Prior research has shown heterogeneity across IRBs on a variety of other matters,[8] but it is difficult to know whether these variations reflect differences in policy or differences in how IRBs handle cases presented. Examination of positive rules, rather than outcomes of cases, may shed light on that question.

In this paper, we investigate IRB policies on disclosing the amount of compensation in recruitment

Megan S. Wright, Ph.D., *is a J.D. candidate (2016) at Yale Law School in New Haven, CT. She earned a Ph.D. in Sociology from the University of Arizona in Tucson, Arizona.*
Christopher T. Robertson, J.D., Ph.D., *is an Associate Professor at the James E. Rogers College of Law, University of Arizona, a Visiting Professor at Harvard Law School (2013-2014), and an affiliate with the Edmond J. Safra Center for Ethics at Harvard. He earned a J.D. at Harvard Law School in Cambridge, MA, and a Ph.D. in Philosophy at Washington University in St. Louis, MO.*

materials from the top 100 institutions by receipt of NIH funding in 2012. We find wide heterogeneity, and conclude by recommending a uniform national policy permitting such disclosures.

Background

Much of the literature on payment for human subjects consists of a debate about the ethics of making any payment at all, and whether payment should be characterized as "compensation," an "incentive," or as a "benefit" to the subject.[9] Ruth Grant and Jeremy Sugarman likely represent a scholarly consensus on the permissibility of using incentives in human subjects research:

> Incentives can be used to recruit subjects in many situations without any ethical qualms where all other ethical criteria are met — that is to say, incentives *themselves* are not the ethical problem here, generally speaking.... We have argued that incentives become problematic when conjoined with the following factors, singly or in combination with one another. Where the subject is in a dependency relationship with the researcher, where the risks are particularly high, where the research is degrading, where the participant will only consent if the incentive is relatively large because the participant's aversion to the study is strong, and where the aversion is a principled one — when these conditions are present, the use of incentives is highly questionable.[10]

Some have argued that in order to treat research participants justly, they should be viewed as wage laborers, which arguably protects their "moral interests," but also allows researchers to use compensation as a recruitment tool.[11]

Other scholars argue that compensating research participants can "seduce" individuals into participating in research when they may otherwise not.[12] This is a concern of many IRB members and researchers who worry that payments or providing health care can unduly influence potential research subjects.[13] In a survey of human subjects protection professionals, Emily Largent and colleagues found more comfort with reimbursing research subjects' expenses incurred to participate in a study and for compensating subjects for their time; there was substantially less support for payment as an incentive or compensation for risk.[14] The authors hypothesize that IRB professionals prefer subjects to volunteer for a study for altruistic reasons,[15] but contend that there is no real difference between payment for reimbursement and compensation and payment as an incentive from the perspective of a potential research subject.[16] As a matter of principle, Largent and colleagues argue that "payment never coerces" and that "payment raises ethical concerns about the validity of consent only when it unduly influences participants by distorting their perception of research risks and benefits. In the absence of evidence that such distortions occur, IRBs should be reluctant to conclude that offers of payment undermine the validity of consent."[17]

The findings of another empirical study indicate that payments do increase individuals' willingness to participate in research, as traditional economics would expect.[18] Empirical research has, however, failed to substantiate the claim that payment information causes irrational choices in human subjects research.[19] In fact, scholars have found that offers of compensation made subjects *more* perceptive about risks.[20]

Prior research has also shown that studies vary considerably as to how much they pay for similar burdens. One study examined the research participant payment amount and consent forms of 467 studies at eleven IRBs and determined that there is significant variation in research subject payment practices (e.g., amount of payment) and no clear explanation for differences between studies, between IRBs, and within studies and IRBs.[21] Following up on unanswered questions, a survey of researchers and IRB chairpersons was conducted to determine what factors influence the decisions to offer payment to research participants and to determine payment amounts. They found that the most important reason for payment is "compensation," but that reimbursement for expenses, a token of appreciation, and incentives for participating also matter.[22] Similarly, prior research with human subjects has shown that they view the prospect of payment as an important, material factor in their decision to pursue a research opportunity.[23]

Much less scholarship has focused on the precise question of whether the amount of compensation should be advertised to subjects deciding whether to pursue an opportunity to participate. Katrina Bramstedt reiterates the FDA guidance that "[a]dvertising study remuneration is not unethical as long as it is not highlighted or emphasized causing it to stand out from other concepts in the advertisement."[24] In her review of studies in a clinical trial database (which potential subjects use to find opportunities to participate in studies), Bramstedt found that "[s]pecific compensation (e.g., dollar amount) for study participation was mentioned in 56 (47%) of 119 advertise-

ments."[25] Bramstedt expressed concern that some studies unethically put too much emphasis on the compensation, contrary to the guidance provided by the FDA. Bramstedt advises that both IRBs and database organizers (because some IRBs approve unethical advertisements) monitor and approve descriptions of research on the databases.[26]

In another study, researchers examined nine universities, along with 23 other research organizations (drug companies, contract research organizations, and independent IRBs), to characterize their policies regarding paying research subjects.[27] Surprisingly, the majority of the organizations in their sample did not have written guidelines. In regards to payment, just under half of the organizations in the sample restrict how payment can appear in advertisements, and four of the organizations do not permit the amount to be placed in recruitment materials, although the materials may specify that subjects will be paid.[28] It is unclear whether such variation in IRB policies exists on a larger scale.

The normative debate about paying human research subjects tends to be conclusory when it comes to the question of advertising compensation amounts. For instance, while Christine Grady asserts that "[a]n IRB should also review the presentation of information about payment in consent documents as well as related advertisements and information sheets," she does not provide suggestions about advertising and recruitment, nor how IRBs should judge payment information on recruitment materials.[29] And in Trisha Phillips' critique of study advertisements that highlight benefits of participation, she argues that "[t]he amount of money offered to subjects and the way in which the offer is presented is relevant to determining whether the quality of the consent is adequate," but does not recommend any specific policies about advertising for IRBs to follow.[30]

No prior research study has characterized the policies of research institutions as they relate to the issue of advertising the amount of payment to human subjects. Nor has any study examined potential associations between those policies and institutional characteristics. This paper will address these gaps in the literature.

Methods

We downloaded from the National Institutes of Health (NIH) website a list of the top 100 research institutions by receipt of NIH funding in 2012. We used NIH funding as an inclusion criterion because it served as a rough proxy of the volume of human subjects research being performed at each institution.

No prior research study has characterized the policies of research institutions as they relate to the issue of advertising the amount of payment to human subjects. Nor has any study examined potential associations between those policies and institutional characteristics. This paper will address these gaps in the literature.

NIH funding is presumably skewed towards medical research, although non-medical research is also subject to the Common Rule and the purview of IRB policies. At the same time, some non-medical institutions may receive sizeable amounts of NIH funding. We coded whether the institutions were medical centers or schools to determine whether there are differences in permissibility of advertising levels of compensation by type of research institution. We took the NIH database entities at face value, although some institutions appeared to be comprehensive universities (which may include medical schools) and others appeared to be more specialized entities, themselves schools of medicine (or public health). Only those entities that explicitly referred to medicine in their name were coded as medical schools. We attempted to find the relevant IRB for each entity listed to code the appropriate policy.

We then recruited and trained two research assistants (second- and third-year law students) to identify each institution's website for its IRB and to search relevant documents until they found a policy that regulated or provided guidelines for advertisements or other recruitment materials for human subjects. The research assistants also provided links to the document, and extracted the relevant text of the policy or guideline, along with a URL and citation. One of the authors (MW) also independently searched for the relevant documents. One author (MW) and the two research assistants independently coded all 100 institutions' policy or guideline with regard to advertising the amount of compensation in recruitment materials. Coding instructions from one of the co-authors (CR) specified that coders were "to carefully distinguish

between the recruitment/advertising stage and the informed consent stage...[and] please look carefully at the distinction between disclosing the amount of compensation, versus disclosing whether there will be any compensation.... We are focused on whether the researcher can say the specific amount of money involved." Coders were given a six-level instrument, to specify whether each institution:

1. prohibits such disclosures,
2. discourages them,
3. has no stated policy (and thus implicitly allows them),
4. explicitly allows them,
5. encourages them, or
6. requires them.

See Table 1 below for examples of institutions that fell into these six categories of policies.

A typical policy in level 3 is one that prohibits researchers from emphasizing the amount of payment, but fails to explicitly state that the amount of payment may be disclosed, as in the FDA guidance. We acknowledge that level 3's notion of implicit allowance involves a step of inference. It is possible, instead, that IRB staffers at such institutions are themselves heterogeneous about how they handle investigator advertisements. At the level of policy, however, we believe it sensible to characterize such institutions as "implicitly allowing" advertising the amounts of compensation.

Then, one of the co-authors (CR) reviewed all three primary coders' excerpts and codes, and coded whether they were in numerical agreement, and if not, then resolved any discrepancies, explaining his decision in writing. After the first 55 institutions were quadruple-coded in this way, the two authors then recoded all 100 policies, in light of the prior codes, which revealed how the independent readers of the policy understood it. In these final codes, the two authors were in agreement 84.88% of the time (kappa=.78), which indicates "substantial agreement" or high inter-rater reliability.[31]

We then calculated frequencies for each of the six possible policy guidelines with regard to advertising the amount of compensation in recruitment materials in order to determine the extent of variation amongst IRBs. Because it was not possible to find information on the policies for 11 institutions (by internet searches or query emails sent from one of the research assistants to the particular IRB), only 89 institutions remain in the final sample. These eleven missing institutions are distinct from the institutions we coded as "level 3," which had an accessible policy relating to advertising materials, but did not specifically address whether the amount of compensation could be stated therein.

Table 1

Codes with Examples of Institutions and Policy Language

Code	Institution	Policy Language
1. Prohibit	New York University School of Medicine	Researchers may not "specify exact monetary compensation amounts."
2. Discourage	University of Wisconsin Madison	"If participants will be paid for their time/effort, it is recommended that the wording 'Compensation Available' be used in recruitment materials, rather than specifying a specific amount. Statements of payment should not be in larger type than the rest of the ad."
3. Implicitly Allow	Harvard University School of Public Health	"THE ADVERTISEMENT: Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type" .
4. Explicitly Allow	University of North Carolina Chapel Hill	"Any advertisement … may include, where appropriate: A straightforward and truthful description of the incentives to the subject for participation in the study (e.g., payment)."
5. Encourage	University of Pennsylvania	Recruitment materials should include the following information: "a description of the compensation/reimbursement. Recruitment materials should NOT include…Overemphasis on compensation but should not emphasize the payment or the amount to be paid."
6. Require	Albert Einstein College of Medicine Yeshiva University	"If remuneration is offered, give actual or at least ball park amounts; e.g. up to.... Payment guidelines are available through the CCI/IRB administration offices."

Results

Our review of the top 100 institutions found that the majority permit investigators to advertise the amount of compensation, but simply regulate the placing of undue emphasis on the amount of payment in recruitment materials (such as by bolding or highlighting payment), a rule which parallels the FDA's guidelines for human subjects research for filings before that agency. Table 2 summarizes our results.

Of the 89 NIH-funded institutions in 2012 in our sample, 8 (8.99%) forbid investigators from disclosing the amount of compensation in recruitment materials; 5 (5.62%) discourage disclosing the amount of compensation; 45 (50.56%) implicitly allow disclosing the amount of compensation; 20 (22.47%) explicitly allow disclosing the amount of compensation; 9 (10.11%) encourage disclosing the amount of compensation; and, 2 (2.25%) mandate disclosing the amount of compensation in recruitment materials. If we group institutions' policies by rough valence, about 15% forbid or discourage disclosures; three quarters (73%) implicitly or explicitly allow; and 12% encourage or mandate.

We analyzed whether there were differences by type of research institution as to whether researchers are permitted to advertise the amount of compensation to potential research participants. Specifically, we investigated whether medical schools or centers would differ from other institutions (i.e., universities and colleges). There were 24 (26.97%) medical schools or centers in our sample institutions, and 65 (73.03%) institutions that were not specialized as medical schools or centers. With 16.67% of medical schools forbidding or discouraging advertising compensation amounts, and 13.84% of the other institutions doing so, we found no significant difference ($\chi 2$ (1)=0.1118, p=0.738).

Additionally, we investigated whether the rank of institution by receipt of NIH funding was associated with institutional IRB policies. We divided the institutions in our sample into quartiles by annual funding, and found that the lower two quartiles of institutions in our sample are much more likely than the upper two quartiles to have policies that implicitly allow (level 3) advertising compensation (65.12% of institutions in the lower half of the sample have such a policy compared to 36.96% of institutions in the upper half). In contrast, the upper two quartiles are more likely to explicitly allow (level 4) advertising compensation than the lower two quartiles (34.78% compared to 9.3%). These differences are large and statistically significant ($\chi 2(15)=25.936$, p=0.039), although the practical distinction between implicit and explicit permission may be minor. When dichotomizing whether an institutional policy permits or does not permit advertising compensation, there is no significant difference between institutions by rank of NIH funding, however ($\chi 2(3)=1.299$, p=0.729).

Table 2

Frequency and Percentages of IRB Policies on Advertising Compensation

Code	Frequency	Percent	Cumulative Percent
Prohibit	8	8.99	8.99
Discourage	5	5.62	14.61
Implicitly Allow	45	50.56	65.17
Explicitly Allow	20	22.47	87.64
Encourage	9	10.11	97.75
Mandate	2	2.25	100
Total	89	100	

Discussion

Our study has shown that there is substantial heterogeneity in IRB policies about specifying the amount of compensation in recruitment materials, with a significant portion requiring or encouraging what another significant proportion forbids. On the whole, over 85% of the research institutions in our sample permit such disclosure, but there is sizeable variation even amongst these institutions. The majority policy (level 3, 51%) is in accordance with the FDA guidance document's silent permission, without imposing additional written specifications; however, the other half of institutions in the sample vary in some way from this guidance, either explicitly telling researchers they can specify the amount of compensation, recommending that researchers do so, recommending that researchers do not do so, or forbidding or mandating such disclosures. Almost equal percentages of institutional policies forbid and discourage such disclosure as do encourage or require, forming a bell-shaped distribution of policies.

It is unclear what explains or justifies such variation. One could attempt to explain this heterogeneity in terms of an underlying heterogeneity in the facts on the ground. IRBs were originally designed as a system of local peer-review,[32] and some argue that there remains a need for local IRBs to reflect local values and concerns.[33] It is possible that some institutions have overall more vulnerable populations than other institutions. If research in sensitive topical areas such as substance abuse and treatment or psychiatric conditions, or

research that recruits from populations such as the drug dependent, homeless, or mentally ill, were clustered geographically, then local IRBs (e.g., those in large, urban areas) may develop distinctive policies to protect these populations. It is not clear, however, that the research performed and subjects recruited in the same major metropolitan area are so very different as to warrant research institutions in those areas having different IRB policies, although this variation was found in our sample.

Shea contend that because IRBs are set up to deal with medical research rather than social science research, IRB members "apply regulatory provisions to such research [field research] that are inappropriate to its own methodological presuppositions."[35]

Recommendations

The federal government has recently acknowledged the need to reduce ambiguity and delay for investigators,[36] something that is exacerbated by heterogeneity

There should be a single rule about the permissibility of advertising the amount of compensation in recruitment materials. The Common Rule is silent on this and many other matters, leaving local IRBs to fill in the gaps. Although IRBs need to be able to reflect local values and concerns, with regard to this particular policy, wide IRB discretion may be a sub-optimal form of regulation.

If the heterogeneity in this particular IRB policy is not due to deliberative, well-considered choices reflecting local concerns or values, it may be that the variation in policies regulating research and purporting to protect human subjects are a function of which institution happens to control, and perhaps which staff members happened to write, the relevant policy. It is possible that the human subject populations are not dissimilar, but instead that some universities have more paternalistic values than others.[34]

However, our study has also shown that the more elite institutions as measured by receipt of NIH funding are more likely to have policies that explicitly allow investigators to advertise the amount of compensation research subjects will receive. In contrast, the less elite institutions are more likely to adhere to the FDA guidance on recruiting human subjects, implicitly allowing investigators to disclose compensation at the recruitment phase of research. Still, such variation is relatively inconsequential, compared to the differences at the poles, where some institutions forbid what others require.

Additionally, our study has demonstrated that there is no statistically significant difference between medical and non-medical research institutions as to whether advertising specific amounts of compensation is permitted by a particular IRB. It is likely that medical research has a greater degree of risk to the human subjects than social/behavioral science research, but such a distinction is not driving variance for this specific policy. Dvora Yanow and Peregrine Schwartz-

in IRB policies. We propose a way in which this heterogeneity in IRB policies about advertising amounts of compensation should be resolved.

First, there should be a single rule about the permissibility of advertising the amount of compensation in recruitment materials. The Common Rule is silent on this and many other matters, leaving local IRBs to fill in the gaps. Although IRBs need to be able to reflect local values and concerns,[37] with regard to this particular policy, wide IRB discretion may be a sub-optimal form of regulation. Current heterogeneity in such policies may impede multi-center research and hinder the movement of researchers across institutions, and may also consume scarce local resources in the efforts to make, disseminate, and enforce all these disparate rules. Additionally, heterogeneity in the substance of rules can create an appearance of arbitrariness, which may undermine the perceived legitimacy of human subjects regulation, for both human subjects and researchers. The FDA's guidance on advertising amounts of compensation does provide a focal point nationwide on this particular question. However, it does not apply outside the research that is within the FDA's regulatory ambit, and it may be too vaguely worded to provide sufficient direction about the permissibility of advertising amounts of compensation for research participation. Thus, although the FDA guidance seems to have created a minor consensus, it is incomplete.

Second, we suggest that the single rule should explicitly permit investigators to disclose in recruitment materials the specific amount of compensation

for study participation. Importantly, when there are significant risks to a study, they should also be disclosed in recruitment materials, alongside the amount of compensation, with similar emphasis. From the perspective of human subjects, these disclosures of material information should be allowed. Subjects need to give voluntary informed consent to participate.[38] However, as the FDA has recognized, the informed consent process actually begins at recruitment.[39] Recruitment is a key stage in the research process in which the subject must make an initial decision about whether to pursue a given opportunity to participate in research. Should she take the time to return a phone call, or click through a link, or respond to an ad in the newspaper, or even travel across town to attend an in-person screening?

IRB policies that prohibit or discourage disclosures of the amount of compensation in recruitment materials force potential participants to guess as to whether the amount of payment will make it worthwhile for them to invest their time and effort in a study. Such guesses as to the amount of payment are likely to be unreliable, creating both false positives and false negatives at this preliminary stage. Proscriptive IRB policies may result in uninformed refusals by persons who wrongly assume that the hidden payment will be too small to be worthwhile, and they also may result in preliminary uninformed decisions to pursue an opportunity by those who wrongly assume that the hidden payment will be high enough to be worthwhile. Relatedly, IRB policies that prohibit or discourage disclosures of the amount of compensation in recruitment materials may unintentionally impose costs on the human subjects the IRB is trying to protect. Potential participants for whom compensation matters to their decision to participate in a study may spend time investigating a research study that they would have quickly declined participating in if they had known the amount of compensation.

Moving to consider the perspectives and legitimate interests of researchers, disclosures about the amount of compensation for study participation should likewise be permitted. One might argue that investigators themselves have autonomy and academic freedom interests, deserving of consideration.[40] Additionally, if a researcher proposes to use a particular mechanism for recruiting human subjects, that is a *prima facie* reason for supposing that the mechanism has instrumental value for scientific progress. For example, there are situations where researchers and research-funders decide that offering a particularly generous level of compensation in an advertisement is required in order to recruit a sample that is representative of a difficult-to-reach population and sufficiently robust to avoid a selection bias. Of course, these investigators may be wrong, but IRBs owe some deference to the methodological expertise of their investigators.[41]

Still, such IRB deference to investigators should not be absolute; the IRB process exists to superintend the research process in order to protect human subjects. Researchers face immense pressure in competition for research funding, and this may result in research recruitment designs that are less scientifically valid. This concern, however, can be allayed due to other parts of the IRB process. IRBs weigh scientific validity in assessing concerns for the welfare of human research subjects, and at least one IRB member needs to have scientific expertise.[42] Prior research has shown that many of the biomedical scientists on IRB committees scrutinize the proposed research for scientific merit.[43] If the research is not scientifically valid or increases risks relative to benefits, then the IRB can deny approval.

Therefore, there is no need for a blanket rule prohibiting disclosures of payment information; IRBs can instead request that researchers justify their payment amounts and recruitment materials in their request for research approval, and IRBs can determine whether the payments are likely to exert undue influence. To the extent that the IRB is concerned that the amount of compensation will be an undue influence, the IRB can require that it be reduced or may preclude investigators from giving it inappropriate emphasis in recruitment materials. IRBs may also require that such information be balanced by information about the risks of the research. Moreover, potential subjects will learn more about the risks during the informed consent stage, blunting the concern that they would be somehow unduly or inappropriately influenced.

Acknowledgements

We appreciate the research support of Stephanie Swift and Jayme Yamaguchi, and funding from the James E. Rogers College of Law at the University of Arizona.

References

1. 45 C.F.R. § 46 (2009).
2. National Science Foundation (NSF), "Frequently Asked Questions and Vignettes: Problems and Advice on Dealing with Them: What Issues Arise Concerning Compensation," *available at* <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp#s> (last visited July 25, 2014); E. A. Largent, C. Grady, F. G. Miller, and A. Wertheimer, "Money, Coercion, and Undue Influence: Attitudes about Payments to Research Participants," *IRB: Ethics & Human Research* 34, no. 1 (2012): 1-8, at 1; E. Largent, C. Grady, F. G. Miller, and A. Wertheimer, "Misconceptions about Coercion and Undue Influence: Reflections on the Views of IRB Members," *Bioethics* 27, no. 9 (2013): 500-507, at 500.
3. See NSF, *supra* note 2.
4. U.S. Food and Drug Administration (FDA), U.S. Department of Health and Human Services, "Recruiting Study Subjects – Information Sheet," *available at* <http://www.fda.gov/Regu-

latoryInformation/Guidances/ucm126428.htm> (last visited July 25, 2014).
5. See Largent et al. (2013), *supra* note 2, at 500-501, and 507.
6. The current Common Rule and subsequent guidance from federal agencies following the Common Rule has a "protectionist ethos" meant to protect human subjects from potential risks of research and also from researchers who may unintentionally exploit their subjects. See L. M. Henry, "Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects," *Journal of Law, Medicine & Ethics* 41, no. 2 (2013): 411-423; D. O'Connor, "The Apomediated World: Regulating Research When Social Media Has Changed Research," *Journal of Law, Medicine & Ethics* 41, no. 2 (2013): 470-483, at 476-477. However, scholars have reported research subjects' concerns about the IRB. As Rothman notes, "[P]atients...want to make their own calculations of risks and benefits and to decide for themselves, without the veto power of an IRB, whether a protocol is worth entering." D. J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York: Aldine de Gruyter, 2003): at 252.
7. Such restrictions on providing information may also infringe on the investigator's speech, not unlike the regulations on advertising the prices of alcohol, which the Supreme Court struck down as violating the First Amendment. See *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (Stevens plurality). Also analogously, in a pharmaceutical case, the Supreme Court emphasized that they have long "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002).
8. See Rothman, *supra* note 6, at 251; D. M. Maloney, *Protection of Human Research Subjects: A Practical Guide to Federal Laws and Regulations* (New York: Plenum Press, 1984): at 222-224. For examples of variation in how IRBs classify risks for multi-center studies, see L. A. Green, J. C. Lowery, C. P. Kowalski, and L. Wyszewianski, "Impact of Institutional Review Board Practice Variation on Observational Health Services Research," *Health Research and Educational Trust* 41, no. 1 (2005): 214-230; R. McWilliams, J. Hoover-Fong, A. Hamosh, S. Beck, T. Beaty, and G. Cutting, "Problematic Variation in Local Institutional Review of a Multicenter Genetic Epidemiology Study," *JAMA* 290, no. 3 (2003): 360-366; J. Mansbach, U. Acholonu, S. Clark, and C. A. Camargo Jr., "Variation in Institutional Review Board Responses to a Standard, Observational, Pediatric Research Protocol," *Academic Emergency Medicine* 14, no. 4 (2007): 377-380; B. Revina, L. Deuel, A. Siderowf, and E. R. Dorsey, "Local Institutional Review Board (IRB) Review of a Multicenter Trial: Local Costs without Local Context," *Annals of Neurology* 67, no. 2 (2010): 258-260; H. Silverman, S. C. Hull, and J. Sugarman, "Variability among Institutional Review Boards' Decisions within the Context of a Multicenter Trial," *Critical Care Medicine* 29, no. 2 (2001): 235-241; C. C. Vick, K. R. Finan, C. Kiefe, L. Neumayer, and M. T. Hawn, "Variation in Institutional Review Processes for a Multisite Observational Study," *American Journal of Surgery* 190, no. 5 (2005): 805-809.
9. M. Meyer, "Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem," *Administrative Law Review* 65, no. 2 (2013): 237-298.
10. R. W. Grant and J. Sugarman, "Ethics in Human Subjects Research: Do Incentives Matter?" *Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine* 29, no. 6 (2010): 717-738, at 732-733.
11. T. Ackerman, "An Ethical Framework for the Practice of Paying Research Subjects," *IRB: Ethics and Human Research* 11, no. 4 (1989): 1-4; H. F. Lynch, "Human Research Subjects as Human Research Workers," *available at* <http://ssrn.com/abstract=2296100> (last visited September 7, 2013).
12. See, for example, T. B. Phillips, "Money, Advertising and Seduction in Human Subjects Research," *American Journal of Bioethics* 7, no. 2 (2007): 88-90.
13. See Largent et al. (2012), *supra* note 2.
14. *Id.*
15. *Id.*
16. See Largent et al. (2013), *supra* note 2, at 501.
17. *Id.*, at 501. For a similar argument, see A. Wertheimer and F. G. Miller, "Payment for Research Participation: A Coercive Offer?" *Journal of Medical Ethics* 34, no. 5 (2008): 389-392.
18. J. P. Bentley and P. G. Thacker, "The Influence of Risk and Monetary Payment on the Research Participation Decision Making Process," *Journal of Medical Ethics* 30, no. 3 (2004): 293-298.
19. See, for example, S. D. Halpern, "Towards Evidence Based Bioethics," *BMJ* 331, no. 7521 (2005): 901-903.
20. See Bentley and Thacker, *supra* note 18.
21. C. Grady, N. Dickert, T. Jawetz, G. Gensler, and E. Emanuel, "An Analysis of U.S. Practices of Paying Research Participants," *Contemporary Clinical Trials* 26, no. 3 (2005): 365-375.
22. E. Ripley, F. Macrina, M. Markowitz, and C. Gennings, "Why Do We Pay? A National Survey of Investigators and IRB Chairpersons," *Journal of Empirical Research on Human Research Ethics* 5, no. 3 (2010): 43-56.
23. C. L. Tishler and S. Bartholomae, "The Recruitment of Normal Healthy Volunteers: A Review of the Literature on the Use of Financial Incentives," *Journal of Clinical Pharmacology* 42, no. 4 (2002): 365-375; see Phillips, *supra* note 12.
24. K. A. Bramstedt, "Recruiting Healthy Volunteers for Research Participation via Internet Advertising," *Clinical Medicine & Research* 5, no. 2 (2007): 91-97, at 96.
25. *Id.*, at 93.
26. *Id.*, at 95-96.
27. N. Dickert, E. Emanuel, and C. Grady, "Paying Research Subjects: An Analysis of Current Policies," *Annals of Internal Medicine* 136, no. 5 (2002): 368-373.
28. *Id.*
29. C. Grady, "Payment of Clinical Research Subjects," *Journal of Clinical Investigation* 115, no. 7 (2005): 1181-1187, at 1686.
30. See Phillips, *supra* note 12, at 90.
31. A. J. Viera and J. M. Garrett, "Understanding Interobserver Agreement: The Kappa Statistic," *Family Medicine* 37, no. 5 (2005): 360-363.
32. See Rothman, *supra* note 6, at 90.
33. See, for example, L. Stark, "Victims in Our Own Minds? IRBs in Myth and Practice," *Law & Society Review* 41, no. 4 (2007): 777-786.
34. Some paternalism might border on what Largent and colleagues call "pseudo-paternalism." This occurs when IRBs "[prohibit] people from doing what is actually in their interests by their own reasonable lights." See Largent et al. (2013), *supra* note 2, at 505.
35. D. Yanow and P. Schwartz-Shea, "Reforming Institutional Review Board Policy: Issues in Implementation and Field Research," *PS: Political Science and Politics* no. 3 (2008): 483-494, at 491.
36. Department of Health and Human Services, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Researchers," *Federal Register* 76, no. 143 (2011): 44512-44531.
37. See Stark, *supra* note 33, at 783.
38. 45 C.F.R. § 46.116 (2009).
39. See FDA, *supra* note 4.
40. A survey conducted in the 1970s revealed that "a substantial minority of researchers felt that the review is an unwarranted intrusion on a researcher's autonomy, that IRBs get involved in inappropriate areas, that IRBs make judgments they are not qualified to make, and that IRBs impede research." See Maloney, *supra* note 8, at 224.
41. For a discussion of how it was once presumed that methodological training would reduce unethical research, see K. Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics," *Qualitative Sociology* 27, no. 4 (2004): 391-414, at 393.
42. 45 C.F.R. § 46.107(c) (2009). See also Rothman, *supra* note 6, at 90.
43. See Maloney, *supra* note 8, at 222.