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An Assessment of the Human Subjects Protection Review Process for Exempt Research

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Jonathan D. Loe, D. Alex Winkelman, and Christopher T. Robertson

I. Introduction

The Common Rule is the federal regulatory scheme for the protection of human subjects in research.[1] It requires that most medical research involving human subjects undergo review by an Institutional Review Board (IRB) and be subject to robust informed consent procedures. However, certain categories of research are considered so low risk as to be exempt from the regulation.[2]

Significant portions of health research are exempt. For example, behavioral research about how physicians understand scientific information, and about why patients may fail to adhere to treatment regimens, often relies on interviews or surveys of patients or physicians.[3] A considerable body of epidemiological and health economic research uses existing data, anonymized to protect patient privacy — another exempt category.[4] Studies of Medicaid and Medicare, as public benefit programs, are exempt too. Proposed changes to the Common Rule would add research using biospecimens to the exempt categories, an important area given the successes of genomic research and the potential for personalized medicine.[5]

Exempt and non-exempt research are substantially different. Fundamentally, the entire Common Rule — the nexus of federal regulation of research— is inapplicable to exempt research projects. For exempt research, federal law does not require elaborate informed consent procedures or documentation thereof.[6] Thus, exempt projects do not require local oversight by an IRB, which means that these projects can be administered more quickly and more flexibly. For even relatively minor changes to a recruitment protocol or survey instrument, non-exempt research requires full IRB approval, and even without changes, requires "continuing review" at least once per year.[7] Overall, an exempt project can be started more quickly, can be changed more flexibly, and can have fewer documentation requirements than non-exempt research.

Federal regulations provide criteria for determining whether research is exempt, but do not currently specify a procedure for making that determination. The Department of Health & Human Services ("DHHS") Office of Human Research Protections ("OHRP") does recommend that researchers not be permitted to make that determination themselves.[8] In practice, local IRBs and their staff do so instead. Thus, unlike a determination that a given project is not human subjects research at all–which puts it outside the Common Rule — "exemption" currently functions as a third level of IRB review, below expedited and full review.

Changes to this system were recently proposed by DHHS. Together with the other federal agencies that implement the Common Rule, it announced a Notice of Proposed Rulemaking ("NPRM") that would signifi-

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cantly revise portions of that rule.[9] It would add new categories of exempt research, exclude from regulation some currently exempt research, and change the exemption procedure to allow researchers to make exemption determinations themselves, using a DHHS-provided web form that has not yet been completed.[10]

To inform these proposed revisions and provide a basis for developing a universal form, our research team sought to assess the current state of how exempt research is reviewed and regulated. We conducted an empirical review of the policies and procedures of the top 50 institutions — based on total NIH funding in the past year — for reviewing putatively exempt research. We found wide and unexplained variation across these institutions. Further, we found that the current submission and review procedures at many institutions impose significantly more responsibilities on investigators than those required at other institutions, without clear benefits to subjects. The DHHS's proposed rule changes are thus a timely reform. We therefore look to some specifics of institutional forms for insight into how DHHS might design its standard form.

In Section II of this paper, we lay out the legal framework surrounding IRB regulation of exempt research. In Section III, we describe the methods we used in conducting our study. In Section IV we lay out the results of our study. In Section V we describe the conclusions that can be drawn and some possible reforms for IRBs to reduce unnecessary work for researchers while still effectively protecting the interests of research subjects. In Section VI we discuss DHHS's proposed template for exemption determinations and a Federal Demonstration Partnership effort to pilot such a form.

II. Background

Section 289 of title 42 of the United States Code requires DHHS to enact regulations that mandate the establishment of an IRB at every institution receiving federal funding for human subjects research, to review such research.[11] In response, the DHHS established the Common Rule, 45 C.F.R. 46 Part A. It is the principal federal effort to ensure the protection of the human participants in research, and provides the framework for efforts to ensure that individual researchers design protocols that effectively balance the risks to subjects with the goals of the research. Because so much research relies upon human participation, ensuring those participants' safety is a powerful concern, of importance not just to the individuals, but to the research enterprise.

To inform these proposed revisions and provide a basis for developing a universal form, our research team sought to assess the current state of how exempt research is reviewed and regulated. We conducted an empirical review of the policies and procedures of the top 50 institutions — based on total NIH funding in the past year — for reviewing putatively exempt research. We found wide and unexplained variation across these institutions. Further, we found that the current submission and review procedures at many institutions impose significantly more responsibilities on investigators than those required at other institutions, without clear benefits to subjects. The DHHS's proposed rule changes are thus a timely reform. We therefore look to some specifics of institutional forms for insight into how DHHS might design its standard form.

The Common Rule applies to all human subjects research conducted, supported, or subject to regulation by any federal department unless exempted under section 46.101(b).[12] The OHRP requires all covered institutions to provide assurances that the IRB will review human subjects research and ensure that the research complies with regulations, unless the research is exempt.[13] OHRP recommends that the institution have clear policies in place for the IRB or some other authority to determine if the research constitutes exempt human subjects research.[14] It also requires an accurate determination so that non-exempt research is reviewed, and monitors whether institutions are compliant.[15]

The exempt categories function as safe harbors for categories of research that are considered low-risk. The general categories that qualify as exempt human research are those that:

(1) Involve normal educational practices conducted in established or commonly accepted educational settings.
(2) Involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior where information is not identifiable or damaging.
(3) Involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior of public officials or where federal statute requires continued confidentiality.
(4) Involve collection or study of existing data, documents, records, or pathological or diagnostic specimens if sources are publicly available or if information is recorded so that subjects cannot be identified.
(5) Study, evaluate, or examine public benefit or service programs or changes to those programs.
(6) Involve taste and food quality evaluation or consumer acceptance studies.[16]

Any research falling into one of the above categories is exempt.[17] Other than the OHRP's non-binding recommendation that "investigators not be given the authority to make an independent determination,"[18] nothing in the regulations specifies who must make the determination that given research is exempt — under the law and regulations alone, a researcher could conceivably find that her own research meets an exemption and then move forward without any form of IRB oversight.

Nevertheless, in practice, things are not that simple. Previous research has shown wide variation in IRB decision-making, both at a policy,[19] and individual project level.[20] In multicenter studies, some IRBs have accorded projects exempt status quickly, while others have taken so long to review the research that the researchers gave up on that center.[21] IRBs have been criticized as arbitrary and capricious decision-makers,[22] with a recent book-length treatment of the subject sharpening the point.[23] Despite this, no study that we could find directly analyzes IRB policies regarding exempt research, or their effects on researchers.

This is especially surprising considering the effect of an exempt determination. Not only does exempt research not require IRB review, it is exempt from all the requirements of the Common Rule. 45 C.F.R. § 46.101(a), (b). Although institutions and funders may impose other restrictions on such research, exempt researchers are generally then free to go about their research. Given this potential vacuum of oversight, it is important to assess the processes used to award such status.

III. Methods

We began by accessing a list of the top 50 research institutions by receipt of NIH funding in 2015.[24] The quantity of funding acts as a rough proxy of the amount of health-related human subjects research being undertaken at each institution. We attempted to find the relevant IRB for each entity listed to code the appropriate form and policy. A research assistant (RA) identified each institution's website for its IRB and searched relevant documents until they found the relevant forms required. The assistant also provided links to the document, and extracted the relevant text of the policy or guideline, along with a URL and citation.

Five modes of analysis were used. First, the RA independently coded all 50 institutions with regard to what forms they required for review of a putatively-exempt study. Five categories were used:

1. No application required for exempt research.
2. Specific form required for exempt research.
3. Main application is adapted/shortened for exempt research.
4. Completion of full IRB form required.
5. Main form plus additional documentation required.

Table 1 below lists examples of institutions in each of these categories. We acknowledge some implicit inferences entailed in the distinction between categories 3 and 4. For example, even full forms for non-exempt research may contain fields that are irrelevant and can be left incomplete by investigators. For category 3, the distinction we drew was whether the institutional form or policy specifically directed the investigator to ignore parts of the form if the research was putatively exempt.

Compliance staff and IRBs may also diverge from written policy — for example, in practice requiring less information than the form itself would seem to address. Our review would not capture such practices. For the purposes of this analysis, we focused solely on the policy as written and published to investigators.

After coding each institution into one of the five categories, we then calculated frequencies for each of the five possibilities to determine the variation amongst institutions. Four institutions could not be coded

Table 1
Form Codes with Examples of Form Language

Code	*Institution*	*Form Language*
1. No submission	None	None
2. Specific form	Johns Hopkins University	"Researchers must complete and submit to HIRB an Application for Exemption or an Application for Expedited/Full Board Review."
3. Adapted main form	Northwestern University	"You are encouraged to use the checklists to write your Investigator Protocol in a way that addresses the criteria for approval....Criteria for IRB approval can be found in the "WORKSHEET: Exemption (HRP-312)" for exempt Human Research."
4. Full form	University of North Carolina - Chapel Hill	"Regardless of review type, all applications use the same online submission form."
5. More than full form	Columbia University Health Sciences	"The following information or documentation should be included or attached for new protocols: Justification for exemption (amongst all others)."

because it was not possible to find their forms or policies (by internet searches or query emails sent from one of the authors to the particular institution). University of Southern California has two IRBs with distinct policies, and so was treated as two institutions. Forty-seven forms were thus left in the analysis.

Second, we then sought to compare hospitals, schools of medicine, and other health-focused institutions to more general research centers. Because medical research is generally less likely to be exempt than social science research, we sought to test whether the nature of form was affected by the type of institution. Institutions were categorized by name: medical institutions were those with hospital, medical (medicine), health, or cancer in their names.

Next, we sought to assess the relative time required of an investigator submitting a full form instead of a form tailored to exemption by looking at the number of pages and questions on the respective forms. Two research assistants located the required forms and recorded the number of pages and the total number of questions, and then coded the questions by type. The coders worked independently, and differences were resolved by author JL. With the increasing use of the internet, many institutions use online application forms, which are usually password protected. Thus, in many cases forms were not available for assessment—17 institutional exempt forms could be coded, and 14 full forms. The questions were coded into three types: checkbox, short answer, and extended answer. Questions requiring a sentence or less were coded as "short," while those requiring more were coded as "extended."

The fourth mode of analysis looked at who made the decision on whether research was exempt. As discussed above, although the regulations do not require it, DHHS guidance suggests institutions have someone other than the researcher confirm that research is exempt. There are generally two possibilities: IRB members or compliance staff. Two authors (JL & DAW) independently coded each of the institutions into either category, and another author (CR) resolved any conflicts. Again, four policies could not be found. Examples are shown in Table 3 below.

Here again, we acknowledge that actual practice may vary from our best reading of the policy; in

Table 2
Examples of Question Language

Question Type	*Question Example*
Checkbox	"Will this project be registered on ClinicalTrials.gov? Yes ☐ No ☐
Short answer	"Name of project"
Extended Answer	"Provide a brief description of the proposed research using terms that someone who is not familiar with the science or discipline can understand."

Table 3
Examples of Decision-Maker Language

Code	*Institution*	*Form Language*
1. IRB member	Washington University in St. Louis	"Only the IRB has the authority to determine if the proposed research activities qualify as exempt."
2. Compliance staff	University of California, San Francisco	"CHR staff must review your study and certify that it qualifies for exemption."
3. Unclear or both are involved	Yale University	"Research proposals that may qualify for exemption consideration are reviewed by one or more experienced reviewers who may or may not be voting members of the IRB."

some but not all cases we confirmed our interpretation by contacting the relevant institution. We used institutional contextual cues where appropriate. For example, many institutions referred to their "human subjects protection programs" (an administrative staff function) as distinct from their "IRB" (the body of faculty and community members).

Finally, we assessed institutional policy regarding modifications or amendment to research protocols previously determined as exempt. When a researcher modifies the scope or method of research that has been determined to be exempt from review, that modification could potentially make the research non-exempt. Some institutions thus have policies requiring investigators to submit modifications for approval as continuing exempt research. We looked to see how many institutions imposed this additional submission by coding for policy type, as described in Table 4 below. This was coded with an identical method to the fourth mode of analysis.

IV. Results

Our review of the top 50 institutions found that two-thirds of institutions have a specific form for researchers to use when they are seeking clearance for exempt research, and another 15% adapt the full form to focus on the relevant exemptness-inquiry. However, a significant minority of institutions required the use of full forms.

Table 5 summarizes our results below. Of the 47 IRBs at 46 institutions for which forms were available, 30 (65.22%) have specific forms for exempt research applications, 7 (15.22%) required an adapted version of their main form, 8 (17.39%) require the full IRB application be used, and 1 (2.17%) required additional forms as well as the main form. No institution allowed investigators to proceed with exempt research without submitting a form, which is to say that no institution allows investigators to make the determination themselves.

Table 4
Modification Codes with Examples of Language

Code	*Institution*	*Form/Policy Language*
Any modification requires submission	UC San Diego	"All modifications to a study that has been certified exempt must be submitted to the IRB for prospective review and certification of exemption prior to implementation."
Only substantive modifications require submission	UNC Chapel Hill	"Studies that were determined to be exempt at initial review need not be reviewed again unless substantive changes warrant review at expedited or full board level."
Only changes that affect exempt status require submission	University of Michigan	"You are not required to submit an amendment regarding *exempt* studies unless the proposed change exceeds the scope of the exemption category or if ancillary review is indicated."

Table 5
Frequency and Percentage of IRB Forms for Exempt Research Applications

Code	*Frequency*	*Percent*	*Cumulative Percent*
No submission	0	0	0
Specific form	31	65.96	65.96
Adapted main form	7	14.89	80.85
Full form	8	17.02	97.87
More than full form	1	2.13	100
Total	47	100	

Table 6
Average Number of Pages and Questions for Form Types

	Exempt Form	*Full Form*	*Difference*
Pages	5.15	18.1	12.95
Total Questions	35	103.3	68.3
Checkbox	13.9	41.3	27.4
Short Answer	13.9	35.2	21.3
Extended	7.4	27.4	20

Table 7
Frequency and Percentage of Exempt Status Decision-Maker

Code	*Frequency*	*Percent*	*Cumulative Percent*
1. IRB member	24	51.06	51.06
2. Compliance staff	11	23.41	74.47
3. Unclear or both are involved	12	25.53	100
Total	47	100	

Table 8
Frequency and Percentage of Modification Policy Types

Code	*Frequency*	*Percent*	*Cumulative Percent*
1. Full submission required for any amendments	32	66.67	66.67
2. Full submission required for substantive amendments only	6	12.50	79.17
3. Full submission required for changes to exempt status only	10	20.83	100
Total	48	100	

When considering whether differences existed between medical-focused and general institutions, as described in Section III, our sample consisted of 17 medical institutions and 30 general institutions. We found that 12 (70.59%) medical institutions used a specific or adapted form, versus 26 (86.67%) general institutions, meaning 5 (29.41%) medical institutions use the full form or require even more information versus 4 (13.33%) of the general institutions. Although suggestive of a real-world disparity, these differences are not statistically significant ($x2$=1.812, p=0.178).

Turning to the difference policy makes, we found substantially more effort was required of researchers by the failure to provide a separate form, as shown in Table 6. On average, the forms used for a full application were almost 13 pages longer than those designed specifically for exemption determinations. They required researchers to answer almost three times as many questions, and, on average, 20 more extended-response questions, which are the most time-consuming for an investigator to answer and for an IRB member or staffer to review. Depending on where a researcher happens to work, he or she can experience a quite different process for review of putatively exempt research.

The analysis of the exemption decision-maker revealed that the majority of institutions require review by an actual IRB member (51.06%). When factoring in the knowledge that some of category 3's institutions use an initial staff review with confirmation by an IRB member, a clear minority (23.41%) of institutions rely solely upon compliance staff review. Table 7 summarizes these results.

For the analysis of amendment or modification for exempt research, we found that most institutions required a full amendment application. The first policy category in which the IRB requires that any modification to the protocol requires a submission for review was in place at 32 institutions (66.67%).[25] Only six institutions required submission for substantive modifications (12.50%). Finally, the third category—that review was only required when the change would affect exempt status—was in place at 10 institutions (20.83%).

V. Discussion

We acknowledge some limitations. We again reiterate that practice may vary from policy. Further, many of the IRB forms could not be coded because they are password-protected. This fact may bias our results because the password-protected online forms may be 'smarter' than paper forms and reduce the number of questions as appropriate. We did examine instructions for filling out such forms, and found little evidence of such smart forms, but cannot rule out the possibility. Another possible bias is that our selected sample of top research institutes might be more or less demanding of researchers than the wider population of hundreds of IRBs.

In general, our results suggest a problem of over-compliance: some local institutions have created burdensome policies beyond that required by the Federal Common Rule. Although the Common Rule is admittedly intended to serve as a baseline for institutions, they should be cautious about imposing additional requirements. This is especially so where those requirements impose unnecessary and time-wasting demands upon investigators and IRBs, without corresponding gains for the protection of human subjects. For exempt research, the risk posed to subjects is minimal.

In general, our results suggest a problem of over-compliance: some local institutions have created burdensome policies beyond that required by the Federal Common Rule. Although the Common Rule is admittedly intended to serve as a baseline for institutions, they should be cautious about imposing additional requirements. This is especially so where those requirements impose unnecessary and time-wasting demands upon investigators and IRBs, without corresponding gains for the protection of human subjects. For exempt research, the risk posed to subjects is minimal.

First, a significant minority of institutions require investigators to complete full IRB applications when applying to begin exempt research, which we found means in practice an average of another 13 pages of paperwork and answering 68 additional questions. Moreover, full applications typically require additional information such as scientific review that is

irrelevant to the determination of whether research is exempt, adding to the researcher's task. For example, the Fred Hutchinson Cancer Research Center form asks researchers: "Is it possible that a commercial product or patent could result from this study?" and "What steps will the Principal Investigator of this study take to ensure that each staff member involved is adequately informed about the protocol and their research-related duties and functions—e.g., new staff orientation, weekly staff meetings?" There may be a benefit to the institution from some of these queries, but they are not necessary to determine whether the study is exempt. These additional requirements not only take investigators' time to answer the questions, but can also cause an iterative back-and-forth with IRB compliance staff, if they require modification of answers irrelevant to the exemption determination.

Even among those institutions that have specialized forms, there are wide ranges of application length. Some institutions have a two-page exempt application, while others require as many as 14. Similarly, one institution's full application required researchers to answer 178 questions, while another required 28. Some — but not all — of this disparity can be explained by compound questions and form structure. Nevertheless, just as the federal government is subject to a Paperwork Reduction Act, research universities should similarly consider and carefully justify paperwork burden.[26]

We received anecdotes from scientists at institutions requiring a full form. They report that they routinely spend seven hours or more preparing the necessary forms, developing the required exhibits and attachments, securing the relevant signatures including those from department heads and scientific peer reviewers within their units, and then making revisions based on requests or demands from IRB staff — all simply to obtain an exemption. The process can take weeks. Our review of the institutional policies makes these anecdotes appear realistic and ubiquitous.

The analysis of exemption decision-maker reveals that IRB members are most often called upon to make decisions about exempt status. In itself, this seems unobjectionable: there is no evidence that staff can make a determination on exempt research any quicker or slower than IRB members, or that they err on the side of over-compliance more or less. But even if review by the two groups is of roughly equal accuracy and speed, there is still a negative effect on research. Time spent considering exempt protocols may also delay consideration of other non-exempt proposals, where there may be substantial risks to human subjects. Further, because the majority of IRB members are themselves scientists, this workload creates a secondary burden on science.

Requirements that investigators prepare and submit requests to modify an exempt research project are in place at a majority of institutions. A substantial majority of institutions require the submission of a new application for any changes to the research protocol. This is so even where the change has no bearing on the exempt status, or where the change is of a minor nature. For example, a researcher using online surveys in her protocol who had intended to use one survey service provider when she initially applied but later wanted to use another platform, would have to submit another IRB application to do so. On the margin, some researchers might rationally choose to forgo the paperwork burden and continue using a protocol that is scientifically suboptimal.

We also found some clear incoherence in the institutional policies. For example, several institutions require elaborate complete IRB applications for the initial application, including attachments showing the survey instrument and securing signatures for scientific peer review. However, once an exemption determination is made, the investigator is allowed to modify the protocol without further submission or review, unless it would change exemption status, a determination that the investigator is then allowed to make for herself. Thus, the original survey instrument and scientific peer review may be utterly irrelevant to the scientific study ultimately performed.

Reflected in all the avenues of analysis discussed above is substantial heterogeneity among institutional policies towards exempt research. The heterogeneity is unexplained by any logical principle. Although one justification for IRB flexibility and individual review is an understanding of local conditions, we were unable to identify any such meaningful trends.[27]

Over-compliance is a phenomenon that has been discussed elsewhere. In the environmental realm, corporations sometimes lower emissions beyond that required by regulation. Scholars have presented theoretical models for why companies may do so, if they can thereby satisfy consumer preferences.[28] That is, by exceeding the required standards, corporations may be seeking a 'green' reputation.[29] This concept loosely translates to the research realm. While institutions typically do not advertise their human subjects' protection programs as a point of difference, they can benefit from strong regimes in the event of research gone wrong, especially if highly-publicized. Thus, they may be over-complying as a way of limiting reputational damage. On the other hand, in the market for scientific talent, institutions must also be careful to avoid a reputation for being burdensome.

It could instead be that DHHS is itself driving this effect. For example, Shimshack and Ward documented over-compliance with environmental regulations in the U.S. pulp and paper industry.[30] They found that enforcement was a significant driver of this phenomenon, provoking many compliant or over-compliant plants to reduce their discharges even further.[31] DHHS enforcement can be severe: after the death of a subject at Johns Hopkins, OHRP suspended all federally supported research projects at the institution for several days.[32] IRBs are normally nested within wider research compliance offices, demonstrating the concern with avoiding DHHS enforcement. So it is not surprising that enforcement actions by DHHS — even though exceedingly rare and unlikely to be triggered by putatively exempt research — might be a cause of institutional over-compliance.

Alternatively, it may be that the over-compliance is a result of attempts to head off more onerous regulation. In the domain of indigenous rights, for example, prior research has shown that some states are over-compliant with international treaty obligations, not out of dedication to the treaty goals, but as a form of resistance.[33] By over-complying with some obligations (creating "soft rights"), some nations seek to establish their own vision of indigenous relations and avoid compliance with other obligations ("hard rights").[34] Similarly, IRBs have been criticized for abdicating their responsibility to develop true ethical standards.[35] Seen this way, IRB policies may focus on forms and procedures as a way of avoiding more substantive regulations that require them to engage more fully in hard ethical and scientific questions that might generate more debate.

Finally, but perhaps most likely, some IRBs may be concerned that the DHHS policy towards exempt research inadequately protects the human subjects; they disagree on the merits. These institutions may be attempting to independently assure that the risk to subjects is indeed minimal. Or they may be concerned that collecting less information from researchers would allow non-exempt, or risky, research to slip through the review process. That is, the additional questions may be designed to prevent omission of information that might slip through gaps in the main questions. Thus, the heterogeneity may be driven by variance in perceptions of the risk to subjects, assessments of the ethical responsibilities of the IRB, or levels of risk-tolerance in individual administrators.

VI. Reforming the Rules

DHHS has proposed reforms. In 2011 it issued an Advanced Notice of Proposed Rulemaking signaling changes to the Common Rule,[36] and in 2015 followed up with a Notice of Proposed Rulemaking.[37] The rules signal that DHHS has heard some of the criticisms of the IRB system, and has moved to update the rules to suit the modern context.[38] For example, for multisite studies, the rules will now require the use of central IRB review in most cases.[39]

The proposed regulations also alter the categories of research. First, the previously exempt category for educational tests, survey procedures, and interview procedures would now be excluded from the definition of research entirely if nonidentifable, as would research involving the collection or study of information that has been collected for nonresearch purposes, and program improvement activities.[40]

Second, the NPRM adds new categories of exempt research. Newly exempt research will include research with nonidentifiable biospecimens if collected with a broad consent form, research which was previously not considered human subjects research at all.[41] Also exempt will be benign interventions and collection of nonidentifiable or nonsensitive identifiable data, secondary research with identifiable information collected for nonresearch purposes, and survey research involving identifiable information.[42]

Finally, and perhaps most relevant to the present study, the regulations propose a new method of determining whether research is exempt.[43] Rather than having institutions individually ascertain exemption status, the proposed regulations would depend on a web-based tool to automatically make the determination based on computer-coded logic.[44] Investigators themselves would use the tool, and the result will protect the institution as long as accurate information was provided.[45] The form would output the information provided and the result to allow the institution to maintain records for this purpose.[46] Since IRB members and staff need not be involved in this determination, it could represent a very significant reduction in the workflow for them, and thereby potentially increase their bandwidth to handle proposals for risky research.

Importantly, individual institutions may opt-out of this process.[47] They may thereby maintain the troublesome heterogeneity across institutions, and potentially maintain current institutional requests of investigators not required by DHHS.

DHHS has also not specified what this smart form would actually look like in practice. Thus, it is difficult to assess the impact of the reform. If the form is tailored to the legally-relevant questions and provides an immediate approval or denial of exempt status, it will accelerate scientific research. If the DHHS form, on the other hand, persists in asking for information that is irrelevant to the exempt determination (as many

institutions now do), it may make matters worse off for investigators currently at more tailored institutions.

The Federal Demonstration Partnership has been testing an online 'wizard' to make exemption decisions for member institutions, and DHHS is reportedly considering the adoption of this wizard after a pilot period.[50] The wizard implements many of the principles described above. It guides investigators through a series of queries designed to elicit only the items key to whether the research is exempt, such as whether the information collected will be identifiable. Does the research involve more than surveys? Will the research be minimum risk? Generally, the questions are brief, and easy to understand. Researchers are given a series of yes/no choices, select the appropriate exemption type, and within a few minutes have an answer to whether their research is exempt.

One concern is that some of the questions as currently written involve language taken straight from the regulations, which thus may require intelligent interpretation. One plausible reason for the over-compliance phenomenon may be concern about researchers misunderstanding the regulations. Research institutions typically require training of their investigators, and the exemption tool could itself be a subject of that training. The upfront time investment in understanding the wizard is likely more beneficial than repeated completion of a longer application process for the researcher, and the institutional gains from automated review substantial.

We are hopeful that the new exempt-determination form will improve the process. Its existence will obviate some of the reasons for over-compliance we identify above, and should limit additional institutional burden. The pilot wizard appears to be a hopeful step toward improvement. Still, it has not yet been released in a final form for comment, and the efficacy of the proposed reforms turns in part on its quality.

VII. Conclusion

Institutional policies impose constraints on researchers and lead to heterogeneity between institutions. Accordingly, institutional decisions to deviate from the Common Rule baseline should require more justification. This is especially so where DHHS itself has recognized the unnecessary burden on exempt research and proposed changes that would require even less from institutions than we document here.[49] Our data underlines the need for such reform, and provides guidance as to its future implementation. Hopefully, that reform will be finalized as a new version of the Common Rule, and if so, take advantage of best practices at current IRBs. But in the absence of that regulatory reform, institutions should seize the initiative themselves, and reform their policies to accelerate the process for valuable exempt research to begin.

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13. Dept. of Health & Human Servs., *Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement* (2005); Dept. Health & Human Servs., *Guidance on Research Involving Coded Private Information or Biological Specimens* (2008).
14. *Id.*
15. 45 C.F.R. § 46.103; See also Dept. of Health & Human Servs., "Frequently Asked Questions," *available at* <http://www.hhs.gov/ohrp/policy/faq/45-cfr-46/hhs-ensures-regulatory-requirements.html> (last visited June 22, 2016).
16. 45 C.F.R. § 46.101(b)(1)-(6).
17. 45 C.F.R. § 46.101(a).
18. See *supra* note 8.
19. M. S. Wright and C. T. Robertson, "Heterogeneity in IRB Policies with Regard to Disclosures about Payment for Participation in Recruitment Materials," *Journal of Law, Medicine & Ethics* 42, no. 3 (2014): 375-382.
20. L. A. Green et al., "Impact of Institutional Review Board Practice Variation on
Observational Health Services Research," *Health Services Research* 41, no. 1 (2006): 214-230.
21. *Id.*
22. C. E. Schneider, *The Censor's Hand* (Cambridge: MIT Press, 2015): at 71-105.
23. *Id.*
24. National Institutes of Health, "NIH Awards by Location and Organization," *available at* <http://www.report.nih.gov/award/index.cfm> (last visited June 22, 2016). List was sorted by funding amount, based on the information reported on May 19, 2015.
25. It is possible this number is inflated. Many institutions lacked a clearly stated policy regarding exempt review. Because, by its very nature, exempt research is not subject to further IRB

review, IRBs should not be reviewing changes that do not affect the exempt status.

26. 44 U.S.C. §§ 3501-21. One purpose of the law is to "minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, Federal contractors, State, local and tribal governments, and other persons resulting from the collection of information by or for the Federal Government." *Id.*, at § 3501.
27. Dept. of Health & Human Servs., "IRB Knowledge of Local Research Context," *available at* <http://www.hhs.gov/ohrp/policy/local.html> (last visited December 7, 2015); Federal Policy for the Protection of Human Subjects, 80 *Federal Register* at 53983.
28. S. Arora and S. Gangopadhyay, "Toward a Theoretical Model of Voluntary Overcompliance," *Journal of Economic Behavior & Organization* 28, no. 3 (1995): 289-309; S. Arora and T. N. Cason, "Why Do Firms Volunteer to Exceed Environmental Regulations? Understanding Participation in EPA's 33/50 Program," *Land Economics* 72, no. 4 (1996): 413-432.
29. *Id.*, at 291.
30. J. P. Shimshack and M. B. Ward, "Enforcement and Over-Compliance," *Journal of Environmental Economics and Management* 55, no. 1 (2008): 90-105.
31. *Id.*, at 96-100.
32. R. Steinbrook, "Protecting Research Subjects — the Crisis at Johns Hopkins," *New England Journal of Medicine* 346, no. 9 (2002): 716-720.
33. S. R. Lightfoot, "Emerging International Indigenous Rights Norms and 'Over-Compliance' in New Zealand and Canada," *Political Science* 62, no. 1 (2010): 84-104.
34. *Id.*
35. See Schneider, *supra* note 22, at 107-120.
36. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 *Federal Register* 44512 (proposed July 26, 2011).
37. Federal Policy for the Protection of Human Subjects, 80 *Federal Register* 53931.
38. K. L. Hudson and F. S. Collins, "Bringing the Common Rule into the 21st Century," *New England Journal of Medicine* 373, no. 24 (2015): 2293-2296.
39. *Id.*
40. *Id.*
41. *Id.*
42. *Id.*
43. Federal Policy for the Protection of Human Subjects, *Federal Register* at 53956.
44. *Id.*
45. *Id.*
46. *Id.*
47. *Id.*
48. Dept. of Health & Human Servs., "Transcript of October 20 Town Hall Meeting on Common Rule NPRM," *available at* <http://www.hhs.gov/ohrp/humansubjects/regulations/transcriptoct20townhall.html> (last visited June 22, 2016).
49. Federal Policy for the Protection of Human Subjects, 80 *Federal Register* at 53955.
50. Welcome to NYU's Decision Engine, Federal Demonstration Partnership, *available at* <http://nsprmd.org/fdp/> (last visited June 22, 2016).