

# Currents in Contemporary Ethics

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## Federal Training Requirements for Responsible Research: Not Going Far Enough

In what is clearly an important development related to research integrity and the protection of human research subjects, the U.S. government has instituted two new training requirements as a condition of receiving federal financial support. First, the National Institutes of Health (NIH) is requiring, as a condition of funding, that key research personnel involved in human subject research complete education “in the protection of human subjects.”<sup>1</sup> Evidence that key personnel have completed this training must be provided in NIH grant applications or contract proposals.

The NIH education policy will eventually be superseded by a more broadly applicable instructional policy for the “responsible conduct of research,”<sup>2</sup> which will be promulgated by the Department of Health and Human Service’s Office of Research Integrity and the Public Health Service (PHS). The instructional policy will apply to

all persons engaged in any research or research training with PHS support. Presently, the only version of the policy is in draft form. The final version of the policy was, according to schedule, announced in November 2000, following a period of public comment on the draft version. However, the newly installed Bush administration suspended the final version in February, responding to criticisms that the public comment period wasn’t widely known and the final version of the policy didn’t respond to the few comments that were made. A review and public comment period is now underway, with a final version of the policy anticipated shortly.<sup>3</sup>

Heightened concern over research integrity and human subject protection — as well as the related public policy response of requiring PHS-supported researchers to undergo responsible research training — is a welcome development that is long overdue. In 1998, several well-publicized reports and congressional testimony were released indicating, in part, that researchers and those who were responsible for research review and oversight were inadequately trained on matters pertaining to research

integrity or human subject protection.<sup>4</sup> A follow-up report that was recently published found that extremely little has been done to correct these and other deficiencies.<sup>5</sup>

The new training requirements, coming well over two years since the findings of deficiencies, are a belated attempt to address a deceptively simple problem: educating researchers and those responsible for research oversight about research integrity and protecting human subjects. As is common with many of the federal regulations pertaining to research, however, both the interim NIH education policy and the PHS draft policy appear too ambiguous and ambivalent to solve this problem. A review of the two policies indicates that much more should be done to improve the substantive training requirements and enhance this important development in our nation’s research enterprise.

## The NIH Policy

On June 5, 2000, the NIH published Notice No. OD-00-039, a policy titled, *Required Education in the Protection of Human Research Participants*.<sup>6</sup> The new policy requires that investigators who submit applications for NIH funding must complete an educational program on human subject protection as a con-

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dition of NIH support. The policy took effect October 1, 2000, but is specifically intended as an interim measure that will be superseded by a final PHS policy on responsible research conduct.<sup>7</sup>

As currently worded, the NIH education policy requires that funding applicants provide a “description of education completed” for key research personnel in their initial and renewal applications or contract proposals.<sup>8</sup> The description of the education program is to be included in a cover letter that accompanies the other documentation required for NIH’s post-initial review and pre-award funding procedures. The description will evidence the applicants’ compliance with the education policy. Key research personnel include all “individuals responsible for the design and conduct of the study.”<sup>9</sup> Research personnel who have lesser responsibilities (e.g., data management staff, research assistants) are in all likelihood not subject to the educational requirements.

In response to many inquiries about what would constitute satisfactory documentation that key personnel had completed the required training, NIH has indicated that the letter must include the names of the key personnel responsible for the design and conduct of the proposed study.<sup>10</sup> Additionally, for each named individual, the title of the education program and a one-sentence description of it must be provided.<sup>11</sup> Finally, the letter must be signed by the principal investigator and co-signed by an official of the institution.<sup>12</sup> To simplify matters, at least one NIH agency — the National Institute of Allergy and Infectious Disease — has gone so far as to provide a “sample” or template for the documentation letter.<sup>13</sup>

### The PHS Draft Policy

On July 17, 2000, the Public Health Service and the Office of Research Integrity published *Draft Policy on Instruction in the Responsible Conduct of Research*.<sup>14</sup> The draft policy is intended by the Department of Health and Human Services to help ensure that PHS-

supported researchers undergo basic instruction in responsible research conduct and related federal regulations. Unlike the NIH educational policy, this policy is intended to apply more broadly to “all staff” engaged in research training with PHS funds or working on PHS-supported research projects. For example, the term “all staff” includes not only investigators, but institutional officials who approve PHS grants as well as students, technicians, consultants, research assistants, and others who work on PHS-supported projects, whether or not these staff receive the support themselves.<sup>15</sup> The policy even recommends that secretarial and other support staff receive instruction relevant to their particular responsibilities and roles.<sup>16</sup>

The PHS policy also includes more substantive instructional requirements.<sup>17</sup> For example, the training program must include “core areas of instruction,” such as peer review, human subjects, research involving animals, research misconduct, and conflict of interest.<sup>18</sup> Brief descriptions of the instructional content within each of these core areas are provided in the policy.<sup>19</sup> While a particular instructional format is not mandated, several instructional models are suggested, including self-study, a one-credit academic course, a workshop, or a series of lectures.<sup>20</sup> Significantly, the draft policy does not require that a person who undertakes the instruction demonstrate competency in any core area, instead leaving the decision to test competency to institutions.<sup>21</sup> The draft policy does recommend, however, that the instructional programs include practice and evaluative components.<sup>22</sup>

Conformity with the PHS instructional requirement can be evidenced through a number of mechanisms, including the certification process currently used on PHS Form 398 grant applications, under which applicant investigators and institutions certify compliance with the Public Health Service’s terms and conditions for the grant.<sup>23</sup> Conformity with the instructional requirements can also be evidenced through annual “Reports on Possible

Research Misconduct” provided to the Office of Research Integrity, as well as other mechanisms as yet to be determined for research conducted through contracts rather than PHS grants.<sup>24</sup>

Institutions that apply for or receive PHS funds for research or research training beginning on October 1, 2000 must certify to the agency that the institution will establish and document the requisite instructional program by June 1, 2001.<sup>25</sup> Furthermore, the institution must certify that it will publish its description of the instructional program or make it accessible to research staff, as well as carry out the instruction itself.<sup>26</sup> The institution must also certify that the instruction for existing research staff will be completed by October 1, 2002.<sup>27</sup> Training for research staff hired after the policy’s effective date must be completed within one year of beginning work on research.<sup>28</sup> Once the PHS policy is fully implemented,<sup>29</sup> it will supersede the NIH education policy, so researchers who have satisfied the NIH educational requirements may still be required to undergo additional training.

### Discussion

Both the NIH education policy and the draft PHS instructional policy are a critical and long-overdue first step towards furthering research integrity and, importantly, human subject protection. Just this past year, a government report indicated that almost no improvement had been made since a 1998 report from the Office of the Inspector General of the Department of Health and Human Services had concluded, among a number of important findings, that investigators as well as members of research review committees required much more training in responsible research conduct.<sup>30</sup> In this respect, the NIH and PHS policies may be lauded for doing what the reports did not: galvanizing research institutions into developing training programs or making such programs accessible to research staff. There are, however, a number of concerns about the new policies.

### *Sad comment on state of training*

First, and as a general matter, it is disconcerting that a federal mandate is necessary in order for institutions to provide their researchers and research reviewers with *basic* responsible research training.

Such a decree implicitly suggests that research institutions lack the wisdom or the wherewithal to adequately prepare researchers and research reviewers for responsible research conduct without external guidance or pressure — which is a troubling thought given that the widespread lack of such training and its attendant adverse consequences has been so clearly established and recognized at the highest levels of government.<sup>31</sup>

Unquestionably, responsible research institutions would not permit an investigator to perform blood draws on human subjects, excise tissue from animal subjects, or perform other laboratory experiments if the investigator lacked the requisite qualifications to do these things.

Similarly, good research practice also requires that investigators be minimally trained, for example, on matters as diverse as informed consent for human subjects, authorship responsibilities for publication, and conflicts of interest. That repeated prodding is required in order for research institutions to own up to the importance of this training or *to take constructive measures to implement it* is a regrettable development in light of our nation's checked history pertaining to research.<sup>32</sup>

One small way for research institutions to mitigate the past neglect of responsible research training for staff is to exercise extreme care and diligence in conforming to the training requirements and to go beyond the federal policies and require all research staff, regardless of source of funding, to be trained.

### *An overreliance on self-policing*

A second concern about the new policies is the overreliance on self-policing

by research institutions, which may, in turn, compromise the training requirements as a meaningful safeguard against unethical or irresponsible research practices. As described above, research institutions are only required to provide assurance of their compliance with the new policies through form letters or signed certifications provided to the Public Health Service prior to the award of a research grant or contract funds. These assurances are conceptually similar to those now used by research institutions to evidence compliance with other PHS requirements, such as appropriate initial and continuing review of research, adequate human and animal subject protection, and research integrity.<sup>33</sup>

In essence, the Public Health Service has delegated to research institutions the responsibility for reviewing and approving research undertaken by their own investigators and promoting research integrity. Institutions are also responsible for investigating and interdicting improper research and research misconduct, as well as reporting such cases to their sponsors and to the Office of Research Integrity.

In a real sense then, institutions subscribe to a federally devised “honor code,” by which the institutions stipulate as a condition of federal funding that human and animal subjects will be protected against research risks and that research misconduct will be prevented or scourged.

While this self-policing scheme has existed for nearly two decades, it has been found lacking in important respects during just the past few years. Particular criticism of the current scheme is leveled at the research review committee process, which official reports have concluded require significant reforms.<sup>34</sup>

Under federal law, a research institution must convene a committee whose members meet regularly to review research protocols involving the institution's research staff. The committee must also perform “continuing” reviews of research already ap-

proved to ensure that human subjects are properly protected. Despite these requirements, official reports indicate that the committees' ability to perform their tasks put human subjects at risk, while some commentators clearly suggest that human subjects are not adequately protected under the current scheme.<sup>35</sup>

Related findings point out that these committees may:

- be unable to effectively manage the large volume of research they are expected to review;
- be unable to conduct more thorough reviews of research;
- have a lack of scientific expertise to make informed judgments about the research they review;
- have a lack of objectivity and independence because of conflicts of interest; and
- not be adequately trained to conduct reviews of research.<sup>36</sup>

In its 2000 report, the Office of the Inspector General of the U.S. Department of Health and Human Services indicated that almost no improvements had been made to the research review scheme that would address the “disturbing inadequacies” discovered in its previous review in 1998.<sup>37</sup>

One of the inferences that might be drawn from these findings is that many research institutions are simply incapable of effectively discharging their self-policing responsibilities under current federal regulations pertaining to the protection of human subjects or research integrity.

Another and perhaps related concern is that the absence of more precise regulatory guidance or requirements may leave too much for research institutions to interpret, leading to widely disparate adherence to the federal regulations. Perhaps a history characterized by an abject lack of enforcement of the regulations or interdiction of research abuses may be to blame. For any one of these reasons, the new PHS policy, which relies so heavily on self-policing by research institutions, may be similarly inadequate.

### *Too narrow in application*

A third concern is that the new policies apply *only* to (a) persons who submit applications for NIH grants or contracts<sup>38</sup> or (b) research staff “who conduct research or receive research training with PHS funds.”<sup>39</sup> Thus, research staff who are engaged in research or research training with non-PHS support, such as those supported by other federal agencies, state governments, non-governmental agencies, or private philanthropy, are not required to undergo responsible research training.

The policies’ limited applicability is understandable: Neither the Public Health Service nor the National Institutes of Health have regulatory authority to institute policies for other federal agencies.<sup>40</sup> Nevertheless, limited applicability of the new policies creates a two-tier environment in which unfortunate disparities will result. For example, human subjects in research funded by agencies *other* than NIH or PHS may be disadvantaged because these researchers may be less informed or less thoroughly trained — or not informed or trained at all — in human subject protection.

Similarly, the public or private investment in non-NIH or non-PHS research may be at greater risk because these researchers may be more likely to have their research suspended or terminated due to research abuses or misconduct that might have been prevented or mitigated by appropriate training.

### *Nature and depth of the training*

Fourth, the new policies are problematic because there is little to no indication of the type of training that investigators should be required to undergo. This omission is especially unfortunate because the weaknesses in our current research oversight scheme and the gaps in research knowledge are more understood than they have ever been.<sup>41</sup> The PHS draft policy does list and briefly describe ten “core instructional areas” that should be included in a training program, to the extent these areas are

relevant to an institution’s research programs.<sup>42</sup> The policy also recommends that research staff receive continuing education in order to keep current on updates and maintain “sensitivity to the issues.”<sup>43</sup>

Left unclear, however, are several important matters, which research institutions are free to discern however they wish. These include, for example, whether and under what circumstances research staff should receive training in each of the core instructional areas, or whether and how training should be tailored to a research staff’s role or responsibility in a research project (e.g., whether a laboratory animal-care technician should receive training in data acquisition or sharing, or whether research staff who have no publication role in a project should receive training in responsible authorship).<sup>44</sup>

Ideally, a well-informed and trained research staff requires some immersion in each of the core instructional areas, with particular focus on those areas most relevant to the research staff’s role and responsibilities.

The NIH policy is even less informative than the PHS draft policy, relying on its proffered citations to Web-based educational resources and indicating that “a number of curricula are readily available to investigators and institutions” and that “NIH does not plan to issue a list of ‘endorsed’ programs in human subject protections.”<sup>45</sup>

A related problem (about which the NIH policy is silent) is that under the PHS draft policy, the format of an institution’s training program can be “any educational activity,” such as a course, workshop, seminar, computer program, or self-study.<sup>46</sup> The policy is equally permissive regarding whether or not the institution provide a certain amount of training or whether or not the research staff demonstrate some minimal competence upon completion of the training.<sup>47</sup>

Without further guidance, the expansive definition of “educational activity” may lend itself to widely disparate outcomes both within and between

institutions. For example, some research institutions might choose to offer only self-study training in order to minimize institutional investment in training, regardless of the needs of the research staff. Other institutions may seek the least intensive training program in order to minimize staff down time. In either case, the importance of responsible research conduct, human subject protection, and research integrity is devalued — and researchers may respond in kind when attempting to master the material (or not). Most discomfiting, the completion of an educational activity might actually be construed as *competence* in responsible research, which given the weakness of the NIH and PHS policies simply cannot be assured.

On the other hand, the expansive definition of “educational activity” will allow more prudent institutions to tailor training to the specific knowledge or skill deficits of each staff member and to offer a number of different types of programs. Some institutions might even offer continuing education in responsible research in order to keep their staff informed of new developments or issues in the field. More discerning institutions may choose to require that researchers demonstrate some minimally acceptable competence in any one or more of the core instructional areas, depending on the researcher’s role or responsibility. Of course, the law doesn’t require any of this.

### **Conclusion and Recommendations**

Given the prominence assigned to human subject protection and the gravity of the deficiencies in the current regulatory scheme of research review and integrity, the NIH educational policy and the PHS draft instruction policy are important contributions to this country’s research enterprise. Nevertheless, both policies could be significantly strengthened, either through changes made in the policies or by research institutions themselves. First, research institutions should adopt procedures more stringent

than either of the policies. The new policies establish only minimal requirements for responsible research instruction and actually suggest that institutions “adopt additional goals” consistent with the policies or impose more detailed or broader research requirements.<sup>48</sup> For example, institutions might require that research staff undergo training in all core areas of research, not just those areas relevant to the staff’s role or responsibility. In order to make the most effective use of training, research institutions might also carefully assess knowledge gaps among current and future research staff and tailor training requirements accordingly.

Second, competency in responsible research conduct should be demonstrated by research staff before they are permitted to undertake any research. Institutions might establish differing levels of competency for each of the core instructional areas, tailored to the role or responsibility of the research staff. For example, it may not always be necessary for a research or animal laboratory technician to have the same degree of competency in human subject protection as a principal investigator who undertakes human subject research or a research review committee member. A change in roles or increased responsibilities can be accommodated by requiring continuing or more intensive training. Institutional review boards and research mentors should play a key role in assuring that research staff receive appropriate as well as continuing training as part of the staff’s development and privilege of conducting research.

Third, it is important that responsible research training be required for all researchers, not just those engaged in research funded by the National Institutes of Health or the Public Health Service. This would include researchers funded by other federal agencies, state governments, non-governmental organizations, and private philanthropy. The Common Rule,<sup>49</sup> now applicable to federal agencies, should be revised to include responsible research training as a condition of federal sponsorship of

research. Other mechanisms to encourage uniform adoption of such training should be evaluated, such as national accrediting agencies, professional societies, and licensing authorities. Most importantly, research institutions should take the initiative and require that all research staff, not just those engaged in research funded by NIH or PHS, undergo training. The opportunity to convey the highest regard for responsible conduct to all who are engaged in our country’s research enterprise should not be missed.

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### References

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2. Public Health Service, U.S. Dep’t of Health and Human Services, *PHS Draft Policy on Instruction in the Responsible Conduct of Research*, NIH Guide OD-00-045 (Washington, D.C.: U.S. Gov’t Printing Office, July 17, 2000) [hereinafter cited as PHS, *Draft Policy*]. For purposes of this article, the terms “responsible conduct of research” and “responsible research” will include human subject protection, which is consistent with the PHS draft policy. See *id.* at sec. II, VII(6).
3. Office of Research Integrity, U.S. Dep’t of Health and Human Services, *Notice of Suspension of PHS Policy*, NIH Guide OD-01-020 (February 22, 2001).
4. J. Bell, J. Whiton, and S. Connelly, NIH Office of Extramural Research, *Final Report: Evaluation of NIH Implementation of Section 491 of the Public Health Services Act, Mandating a Program of Protection for Research Subjects* (Washington, D.C.: NIH Office of Extramural Research, 1998): 46–47, 59–60; Office of the Inspector General, U.S. Dep’t of Health and Human Services, *Institutional Review Boards: A Time for*

*Reform* (Washington, D.C.: U.S. Gov’t Printing Office, 1998): 8 [hereinafter cited as OIG 1998 Report].

5. Office of the Inspector General, U.S. Dep’t of Health and Human Services, *Protecting Human Subjects: Status of Recommendations* (Washington, D.C.: U.S. Gov’t Printing Office, 2000) [hereinafter cited as OIG 2000 Report].

6. NIH, *Required Education*, *supra* note 1.

7. *Id.* at “Implementation.”

8. *Id.*

9. *Id.*

10. NIH Office of Extramural Research, “Clarification on Required Education in the Protection of Human Research Participants,” *OER Grants: Current News Flashes & Archives* (September 14, 2000), available on-line at < [http://grants.nih.gov/grants/newsarchive\\_2000.htm#20000914](http://grants.nih.gov/grants/newsarchive_2000.htm#20000914) >.

11. *Id.*

12. *Id.*

13. “Sample Letter to Document Training in Research Conduct,” *NIAID Council News* (September 19, 2000), available on-line at < <http://www.niaid.nih.gov/ncn/newsletters/nl090700/sample.htm> >.

14. PHS, *Draft Policy*, *supra* note 2.

15. *Id.* at sec. IV.

16. *Id.*

17. *Id.* at sec. II.

18. *Id.* at sec. VI(A).

19. *Id.* at sec. VII(1)–(10).

20. *Id.* at sec. III.

21. *Id.* at sec. VI(B).

22. *Id.*

23. *Id.* at sec. X(B).

24. *Id.*

25. *Id.* at sec. X(A).

26. *Id.* at sec. X(A)(2), (3).

27. *Id.* at sec. X(A)(4).

28. *Id.* at sec. IX(B).

29. *Id.* at n.1. Because the PHS instructional policy will eventually supersede the current NIH education policy, most analysis here is reserved for the PHS policy; any relevant differences will be mentioned.

30. OIG 2000 Report, *supra* note 5, at 2.

31. Advisory Committee on Human Radiation Experiments, *Final Report* (Washington, D.C.: U.S. Gov’t Printing Office, 1995): 817 [hereinafter cited as ACHRE, *Final Report*] (recommending the development of effective strategies for changing the existing culture and placing ethics at the center of research conduct, including mandating the “teaching of research ethics”); OIG 1998 Report, *supra* note 4, at 8. See also Bell et al., *supra* note 4, at 59–60.

32. See generally ACHRE, *Final Re-*

port, *supra* note 31, at 81–223 (reviewing ethics in human subject research from the 1940s to the 1970s); *Beyond Consent: Seeking Justice in Research*, J.P. Kahn, A.C. Mastroianni, and J. Sugarman, eds. (New York: Oxford University Press, 1998) (providing some historical background on research exploitation involving vulnerable populations).

33. 45 C.F.R. § 46.103 (2000) (stating in relevant part that “[e]ach institution engaged in research which is covered by this policy, and which is conducted or supported by a Federal Department or Agency shall provide written assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy”). See also 45 C.F.R. § 46.109 (“IRB review of research”); 45 C.F.R. § 46.116 (“General requirements for informed consent”); 45 C.F.R. § 46.113 (“Suspension or termination of IRB approval of research”); 7 U.S.C. § 2131 *et seq.* (“Animal Welfare Act” (1966)); National Institutes of Health, Dep’t of Health & Human Services, Public Health Policy on Humane Care and Use of Laboratory Animals (rev. 1986) (supplying the principles and procedures on the use and care of vertebrate animals in research); 42 C.F.R. § 50.101 *et seq.* (setting forth institutional responsibilities for investigating research misconduct).

34. *Institutional Review Boards: A Time for Reform: Testimony Before the Subcommittee on Human Resources of the House Comm. on Government Reform and Oversight* (1998) (testimony of George Grob, Deputy Inspector General, U.S. Dep’t of Health and Human Services).

35. OIG 1998 Report, *supra* note 4, app. at D-14 (1998) (comments by the Public Citizen’s Health Research Group); see Kahn et al., *supra* note 32, at 166.

36. *Id.* at ii-iii. But see *id.* at app. at D-20, D-30, and D-38 (comments by Applied Research Ethics National Association, the

Association of American Medical Colleges, and the Consortium of Independent Review Boards, criticizing some of the generalizations made in the OIG’s report).

37. OIG 2000 Report, *supra* note 5, at 1–3.

38. NIH, *Required Education*, *supra* note 1.

39. PHS, *Draft Policy*, *supra* note 2, at sec. IV. However, the policy “does not limit the authority of an institution to impose more detailed or broader requirements of RCR [responsible conduct of research] education.” *Id.* In fact, the policy provides that, as part of an institution’s certification of compliance to PHS, the institution describe how the instructional program is “being applied to those research staff not supported by PHS funds.” *Id.* at sec. X(A)(1).

40. See, e.g., OIG 2000 Report, *supra* note 5, at 3 (observing that the Common Rule [or 45 C.F.R. § 46, Subpart A], which serves as the “basis of a common Federal policy on human-subject protections,” is a significant barrier to making the recommended changes pertaining to research oversight because any change to the Common Rule requires the concurrence of all seventeen agencies adhering to the rule).

41. See, e.g., OIG 1998 Report, *supra* note 4. For a sample of other literature demonstrating the extent of our knowledge regarding deficiencies in research oversight or important issues in research integrity, see generally Office of the Inspector General, U.S. Dep’t of Health and Human Services, *Institutional Review Boards: Promising Approaches* (Washington, D.C.: U.S. Gov’t Printing Office, 1998); Office of the Inspector General, U.S. Dep’t of Health and Human Services, *Institutional Review Boards: Their Role in Reviewing Approved Research* (Washington, D.C.: U.S. Gov’t Printing Office, 1998); Office of the Inspector General, U.S. Dep’t of Health and Human Services, *Institutional*

*Review Boards: The Emergence of Independent Boards* (Washington, D.C.: U.S. Gov’t Printing Office, 1998); *Ethical Issues in Biomedical Publication*, A.H. Jones and F. McLellan, eds. (Baltimore: Johns Hopkins University, 2000); Society for Neuroscience, *Responsible Conduct Regarding Scientific Communication* (1st ed.) (1998), available on-line at <<http://www.sfn.org/guidelines/guidelines-Final.pdf>>; J.E. Sieber, *Planning Ethically Responsible Research: A Guide for Students and Internal Review Boards* (Newbury Park, California: Sage Publications, 1992); and Committee on Science, Engineering, and Public Policy, National Academy of Sciences et al., *On Being a Scientist: Responsible Conduct in Research* (Washington, D.C.: National Academy Press, 1995).

42. PHS, *Draft Policy*, *supra* note 2, at sec. VI(A). These include data acquisition, management, sharing, and ownership; mentor/trainee relationships; publication practices and responsible authorship; peer review; collaborative science; human subjects; research involving animals; research misconduct; conflict of interest and commitment; and compliance with existing PHS and institutional policies. *Id.*

43. *Id.* at sec. IX(C).

44. At least the NIH policy suggests that “some [investigators] may elect more intensive study if their work involves especially difficult topics or special populations.” NIH, *Required Education*, *supra* note 1, at “Educational Resources.” But such intensive study should be required, not elective.

45. NIH, *Required Education*, *supra* note 1, at “Educational Resources.”

46. PHS, *Draft Policy*, *supra* note 2, at sec. III.

47. *Id.* at sec. VI(B).

48. *Id.* at sec. IV, V(B).

49. 45 C.F.R. § 46 (Subpart A); but see note 40, *supra*, regarding concerns about the Common Rule.