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Author: Robert J. Kenney Jr.

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How to Conduct Non-Federal Stem Cell Research Without Violating the Federal Stem Cell Funding Prohibition

By ROBERT J. KENNEY JR.

1. Introduction and Summary

On Election Day 2004, California voters approved Proposition 71—the California Stem Cell Research and Cures Initiative—which will raise as much as \$3 billion over ten years to support human embryonic stem cell (hESC) research. The prospect of new sources of major support for hESC research, from California and elsewhere,¹ has revived the discussion of how recipients of federal research funding² can use these sources to conduct research involving human embryonic stem cells without running afoul of the Bush administration's broad prohibition of the use of federal funds in such research. The purpose of this article is to

¹ Two Maryland legislators recently proposed legislation to dedicate \$25 million a year to support stem cell research in Maryland, and reportedly Florida, New Jersey, Wisconsin, Minnesota, and Illinois are considering similar measures. *Baltimore Sun*, "Stem Cell Funding Sought," Dec. 19, 2004.

² The focus of this article is on preventing a spillover of federal research funding to the support of ineligible hESC research. Many institutions that receive federal research funding also receive other forms of federal support (most notably funding to support student financial aid). Although it is possible to imagine circumstances in which such federal nonresearch funding might be deemed to support ineligible hESC line research in some attenuated way, those circumstances are likely to be relatively rare, and are beyond the scope of this article.

Robert J. Kenney Jr. is a partner with Hogan & Hartson LLP, Washington, D.C., and the director of the firm's federal grants practice.

help federally funded research institutions answer that question.

In his first year in office, on Aug. 9, 2001, President George W. Bush announced a prohibition on the use of federal funds to support research using human embryonic stem cell lines (other than a limited number of pre-existing lines satisfying certain prescribed criteria). Soon thereafter, the National Institutes of Health (NIH) established a stem cell registry identifying the hESC lines that meet the criteria in the president's announcement. The president's directive effectively created two categories of human embryonic stem cell research projects—those that can be supported by federal funding ("eligible hESC research") and those that cannot ("ineligible hESC research"). This dichotomy makes it necessary for institutions engaged in ineligible hESC research to build safeguards to prevent federal research funds from being used for such research.

Because the president's prohibition on human embryonic stem cell research is in the form of a funding limitation rather than an outright ban, whether a particular hESC project violates the prohibition will, in most cases, turn on an accounting question—i.e., whether the funds or resources used in the project can be traced to a federal source. In some cases, the answer to this question will be straightforward. Clearly, for example, an institution would be precluded from charging an NIH grant directly for salary costs or expenses associated solely with research on hESC lines not identified in NIH's stem cell registry. It is equally clear that neither the president's announcement nor NIH's implementing guidance contains any prohibition on use of non-federal funds for hESC research. Given the vagaries and misunderstandings surrounding cost accounting under federally sponsored projects, however, there

are many cases in which it will be difficult to be certain that a particular non-federal hESC project has not been supported even partially or indirectly by federal funds.

The principal difficulty arises in mixed funding situations, where an institution involved in hESC research using ineligible lines is also involved in other research for which it receives federal support. Issues also arise where the hESC research uses a facility, equipment, or other resources purchased, built, or developed with directly awarded federal funds. The questions in such situations are many and various: Must eligible and ineligible hESC research be conducted in physically segregated locations, with strictly differentiated sources of supplies and other resources? May laboratory space whose cost is included in the institution's federal indirect cost rate be used for research involving ineligible hESC lines? May equipment or other property purchased with federal funds ever be used in such research? May scientists engaged in such research use institutional core facilities, such as DNA testing laboratories, that are subsidized by federal funds? These and other similar questions must be addressed by any recipient of federal research funding that embarks on ineligible hESC research.

Fortunately, NIH has issued guidance that helps to answer some of these questions. As discussed in more detail below, the NIH guidance essentially states that if an institution strictly follows the federal cost principles applicable to the allocation of direct and indirect (F&A) costs and the charging of F&A cost rates, then those principles will by definition ensure that no costs allocable to ineligible hESC research are supported by federal funds. Under NIH's formulation, grantees generally are not required to maintain segregated facilities or resources for non-federal hESC research, or to account for the direct or indirect costs of such research separately or any differently from other non-federal research.

Most research institutions will find this NIH guidance reassuring and helpful, because it offers a solution to a potentially difficult problem without creating new operational or paperwork burdens. There are, however, three cautionary notes that must be sounded.

First, although the NIH guidance is pragmatic and sensible, the subject of human stem cell research is so highly charged that any federal pronouncement on the subject must be regarded as tentative until it has been tested in the crucible of political and public opinion. One well-publicized case involving ineligible hESC research in a lab supported by federal research funds may be all it takes to cause the White House and NIH to tighten their rules in this area.

Second, although institutions no doubt will be relieved to hear that they need "only" comply strictly with the federal cost accounting principles to which they already are subject, no one should underestimate the difficulty of ensuring such compliance in a manner that will withstand close scrutiny. The OMB cost principles are not hard to grasp in theory, but most research institutions have found that their researchers and administrative staff do not always understand them fully, or follow them strictly. Failure to comply with applicable cost allocation rules is a significant enough problem when it affects only the dollar amounts charged to federal projects. Where such noncompliance also could subject an institution to a legally and politically serious charge of improperly using federal funds to conduct unautho-

ized hESC research, the stakes are potentially much higher.

Finally, there are some funding situations that the general guidance provided by NIH does not address. Although it is possible to make educated guesses as to how NIH and the White House might view such cases, as of yet there is no government guidance that governs all federal funding or support situations that may arise.

Section 2 of this article comments briefly on the possible consequences of violating the prohibition on use of federal funds for ineligible hESC line research. Section 3 summarizes the NIH guidance on the mixed funding question, and section 4 discusses what the guidance means and how it would apply in practice. Section 5 addresses special situations that the NIH guidance does not specifically cover. Finally, section 6 offers recommendations on how to implement the NIH guidance in a way that will minimize exposure to allegations of improper use of federal funds for ineligible hESC line research.

2. Possible Consequences of a Violation

Before addressing the question of what institutions should do to avoid violations of the president's human embryonic stem cell policy, it is worth pausing to consider what the consequences of such a violation might be. Strictly from a legal perspective, the consequences do not appear to be particularly frightening (at least if some reasonable measures are taken to prevent violations), but the political and reputational consequences could be significant.

Neither the president's Aug. 9, 2001, announcement nor NIH's implementing guidance establishes any special penalties to which an institution would be subject if it were to use federal funds to support ineligible hESC line research. As discussed below, the NIH guidance does make it clear that the costs of such research would be deemed unallowable charges to any federal project, so any institution making such a charge to a federal project would at a minimum be obligated to refund the charge, along with the associated indirect costs. More severe consequences obviously could follow, under the False Claims Act or other federal fraud statutes, if an institution were knowingly or recklessly to charge unallowable hESC research costs directly to a federal project. It seems much less likely, however, that a mischarge resulting from a technical accounting misunderstanding would have severe legal consequences—especially if the institution has taken reasonable, good-faith steps to avoid such mischarges.

For most institutions, the possible political and reputational consequences of a violation are likely to be of at least as much concern as the potential legal consequences. Given the high degree of sensitivity surrounding the use of hESCs, no recipient of federal research funding can take lightly the risk of an accusation that it has violated the president's ban on the use of federal funding for prohibited stem cell research. In an extreme case, it is not unimaginable that a violation could lead to a withholding or temporary suspension of federal research funding. At a minimum, therefore, any recipient of federal research funding that is engaged in ineligible hESC line research should be well prepared to show that it has taken reasonable measures to implement the president's prohibition.

3. NIH Guidance on the Federal Funding Prohibition

The NIH, with the technical assistance of the Department of Health and Human Services Division of Cost Allocation (DCA), has developed helpful guidance on the conduct of hESC research in mixed funding situations. This guidance appears in a set of “Frequently Asked Questions” relating to hESC research funding, which is posted on a special NIH “Stem Cell Information” Web page (<http://stemcells.nih.gov>). The most relevant FAQs on the funding subject are FAQs 4, 6, 7, and 8. FAQ 4 is the most important of the four; the other three essentially repeat the principle of FAQ 4 or apply it to more specific situations. FAQ 4 reads in its entirety as follows:

- 4. What if a scientist is conducting research with both Federally fundable and non-Federally fundable human embryonic stem cells?** Scientists who receive Federal funds and study both Federally fundable and non-Federally fundable human embryonic stem cells must charge research costs for study of non-Federal lines only to non-Federal sources of funding. With respect to indirect costs, such as facilities and administrative (F&A) costs, scientists should adhere to the guidelines in *OMB Circular A-21*. This document describes how to keep budget records so as to prevent Federal funds from indirectly supporting research on non-Federally fundable human embryonic stem cells.

Technical guidance provided by the DHHS Division of Cost Allocation states that the cost principles and Cost Allocation Standards contained in OMB Circular A-21, particularly with regard to the treatment of activities sponsored by industry and foreign governments are equally applicable to unallowable stem cell research. The regulations strictly forbid the shifting of costs from these activities to Federally-sponsored activities. Strict adherence to the principles contained in the circular, requires the allocation of indirect costs, also known as facilities and administrative (F&A) costs, to both Federally sponsored and other activities, which would include unallowable stem cell research. Federal policy is clear that no Federal funding may be used, either directly or indirectly, to support human embryonic stem cell research outside the criteria established by the President on August 9, 2001, i.e., it is unallowable. Therefore, the direct costs of such activity must be charged only to non-Federal sources of funding. With respect to F&A costs, institutions engaged in unallowable stem cell work must strictly adhere to guidance contained in OMB Circular A-21. *Strict compliance with cost allocation methodologies described in the circular, including the Cost Allocation Standards, will prevent the shifting of unallowable Stem Cell research costs to Federally sponsored programs. The F&A costs which are allocated to Stem Cell research will not be charged to Federally sponsored activities because the direct costs of the Stem Cell programs are only charged to non-Federal sources of funding. A properly documented F&A proposal utilized in the establishment of F&A rates, should demonstrate that none of the costs of unallowable stem cell research or other unallowable activities have been shifted to Federally sponsored activities.* [Italics added.]

The heart of FAQ 4 is contained in the two sentences italicized above. The first of these sentences states that if an institution follows the applicable federal cost principles, then those principles themselves will “prevent” any shifting of federal funds to ineligible hESC line research. The second sentence makes the point that if the

direct costs of hESC research are allocated properly in accordance with the cost principles, then the indirect (F&A)³ costs associated with that research will automatically be allocated properly as well. This is certainly correct as a matter of cost accounting, as explained in section 4 below.

FAQ 6 essentially repeats the guidance of FAQ 4 in a less formal and more concrete way. Like FAQ 4, FAQ 6 states that there must be an allocation of costs between hESC projects and other projects. FAQ 6 adds that institutions must provide “clear instructions” to investigators concerning the necessity for such allocation and, presumably, how the allocations should be done. FAQ 6 reads as follows:

- 6. I am a university research administrator. One of our NIH-funded investigators would like to use a cell line that was created after August 9th, 2001, and it is not eligible for research using Federal funds. What should I tell the investigator who wants to work with these cells in his laboratory?** Institutions need to provide clear instructions to investigators who conduct research that is “unallowable” under Federal research funding policy. In laboratories where there is both Federal and non-Federal funding, investigators and their staffs must separate allowable and unallowable activities in such a way that permits the costs incurred in the research to be allocated consistently to the appropriate funding source. In your example, for instance, the time and effort of laboratory personnel working on the stem cell line created after August 9, 2001, may not be charged to any Federal grant. Acquisition of equipment, use of cell and tissue culture supplies in the project, and travel to a conference to discuss or present this work likewise may not be Federally supported.

FAQ 7 is also an elaboration of FAQ 4—it does not add any new concepts. It does, however, make explicit the very important point that ineligible hESC research need not be conducted in physically segregated facilities. FAQ 7 repeats the rule that the investigator involved in ineligible hESC line research must “carefully and consistently” allocate to such research all of the costs of performing it:

- 7. I am an investigator who receives NIH funding, and I am planning to derive new human embryonic stem cell lines. Can I conduct the derivations in my laboratory, or do I need to find a non-university funded laboratory to do this work?** You may do the derivation in your university supported laboratory as long as: 1) you carefully and consistently allocate all costs of doing the derivation to a non-Federal funding source; and 2) your university or research center has in place a method of separating the costs of supporting your laboratory so that any of the facilities and administrative (F&A) costs allocable to your new stem cell line work are excluded from the Federal share of the organized research cost base, per the provisions of OMB Circular A-21.

The last pertinent FAQ is FAQ 8, which reads as follows:

- 8. Can you explain what accounting principles are necessary to demonstrate that unallowable charges are not being absorbed by NIH funded research, e.g., indirect costs?** The cost principles contained in OMB Circular

³ The term “facilities and administrative (F&A) cost” is synonymous with the term “indirect cost” under federal cost accounting principles.

lar A-21, <http://www.whitehouse.gov/omb/circulars/a076/trans21final.html> [Editor's note: The Web address in the FAQ document does not link to OMB Circular A-21, an apparent error. Circular A-21 is available at http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html], particularly with regard to treatment of allowable and unallowable costs, contain the necessary guidance. Federal policy is explicitly clear that no Federal funding may be used, either directly or indirectly, to support human embryonic stem cell research outside the criteria established by the President on August 9, 2001, i.e., it is unallowable. Therefore, the direct costs of such work must be charged only to non-Federal sources of funding. With respect to indirect costs, also known as facilities and administrative (F&A) costs, institutions engaged in unallowable stem cell work must be able to demonstrate that none of the costs of supporting this work have been included in the rates established and used to charge F&A costs to Federally funded research.

Again, FAQ 8 does not add significantly to what is already stated in FAQ 4; it appears that it was included primarily for emphasis.⁴

4. Interpreting and Applying the NIH Guidance

As the NIH guidance clearly indicates, NIH and DCA have chosen to test for federal funding of ineligible hESC research solely by reference to the cost principles of OMB Circular A-21 and other applicable federal cost accounting rules. The cost accounting principles behind the NIH guidance may be illustrated using the following example:

University X is engaged in a wide range of federal and non-federal organized research, including some non-federal hESC research using ineligible lines. The university determines that the total direct costs of performing all University X-organized research (e.g., salaries of research personnel, laboratory supplies, directly related travel, cell and tissue cultures, etc.) are \$50 million, of which \$35 million are direct costs of federal projects, \$1 million are direct costs relating to ineligible hESC line research, and \$14 million are other non-federal organized research direct costs. The institution's negotiated organized research F&A rate is 60 percent, reflecting a determination and an agreement with the federal government that for each dollar of the institution's organized research direct costs,⁵ there are on average 60 cents worth of allowable F&A costs (e.g., building and equipment depreciation, maintenance costs, utility costs, library and administrative costs, etc.), for a total of \$30 million. Thus, if an NIH grant were to involve \$100,000 in direct costs, the institution would allocate \$60,000 in F&A costs to the grant and charge NIH accordingly.

The first principle underlying the NIH guidance is that if University X has correctly allocated its direct organized research costs in accordance with OMB Circular A-21, then by definition the \$1 million in direct costs

⁴ It should be noted that although FAQ 4 and FAQ 8 both refer to OMB Circular A-21 (the federal cost accounting principles for colleges and universities), the similar cost allocation provisions of OMB Circular A-122 would apply to nonprofit organizations, and hospital and state grantees would be subject to similar federal cost allocation provisions that are applicable to them.

⁵ Technically, the organized research base consists of "modified total direct costs," or MTDC, which excludes certain subcontract, equipment, and other costs.

that the university has associated with ineligible hESC research will exclude any direct costs funded by federal sources. For example, OMB Circular A-21 contains extensive provisions on the correct method for allocating direct costs of researcher salaries among the projects in which they are involved. If a particular faculty member devotes 20 percent of his or her time and effort to teaching, 50 percent to an NIH grant, and 30 percent to an ineligible hESC line research project supported by non-federal funds, then A-21 would require the faculty member's university salary to be allocated among these three activities in percentages of 20 percent, 50 percent, and 30 percent, respectively. If this allocation methodology is strictly followed, then under the cost accounting principles of A-21 the NIH grant will not bear any part of the direct cost of the faculty member's effort on the hESC project.

This result seems so obvious as to be almost self-evident, but it must be recognized that the logic of A-21 is not the only logic that could be applied in this situation. It also could be argued, referring to the example of the faculty member in the last paragraph, that because NIH pays 50 percent of the faculty member's salary, 50 percent of everything he or she does is supported by federal funds. Under this logic, any faculty member who has accepted even one dollar of federal salary support would be precluded from engaging in ineligible hESC research.⁶

The NIH guidance rejects this logic. In FAQs 6 and 7, NIH indicates that an investigator who receives NIH funding also may be engaged in ineligible hESC line research, as long as his or her salary is allocated between the two activities in accordance with his or her effort.

The second principle underlying the NIH guidance is that if direct costs are allocated strictly in accordance with the applicable federal cost principles, F&A costs automatically will be allocated correctly—i.e., no federal project will bear any F&A costs associated with ineligible hESC line research. In the example of University X, whose F&A rate is 60 percent, each dollar of direct costs of research will be associated with 60 cents worth of F&A costs, and the \$1 million in hESC research will be allocated \$600,000 in F&A costs. If University X has correctly determined that its direct costs of ineligible hESC line research are \$1 million, then according to the NIH guidance the \$600,000 in associated F&A costs also will be "correct"—i.e., it will not be deemed to include any costs supported by federal funding.

Again, although this result seems logical, in the absence of the NIH guidance there would have been other ways of looking at this issue, which would have produced very different results. One such alternative view follows from the premise that because 70 percent of University X's organized research is federal, approximately 70 percent of every dollar of the university's organized research F&A costs is paid for from federal sources. For example, if 100 percent of the salary of a

⁶ A recent *Wall Street Journal* article mistakenly used this logic in describing the federal restriction: "The problem is that any researchers who received money from the federal government for stem-cell research on the old lines . . . can't touch Harvard's [ineligible hESC] cell lines without giving up their federal funding." *Wall Street Journal*, "California Funding to Draw Scientists," Nov. 10, 2004. The mistake was corrected in the following day's edition.

grants administrator earning \$50,000 is allocated to the F&A costs of organized research (as it normally would be), then the F&A recovery under University X's federal organized research grants (which are 70 percent of total organized research) effectively would "pay for" about \$35,000 of the grant administrator's salary.⁷ Under this view of University X's federal funding, the grants administrator would be precluded from being involved in the review or administration of any ineligible hESC line research project, because he or she would be deemed to be supported in part by federal funds. The same restrictive argument of course could be made with respect to virtually all of University X's other organized research F&A costs.

The NIH guidance rejects this argument as well. FAQ 4 makes it clear that if the F&A costs associated with ineligible hESC line research are determined by the normal process of the applicable cost principles (i.e., by applying the government-approved F&A rate to the direct costs of individual projects), then no federal F&A funds will be deemed to have supported the ineligible hESC line research. ("The F&A costs which are allocated to Stem Cell research will not be charged to Federally sponsored activities because the direct costs of the Stem Cell programs are only charged to non-Federal sources of funding.") In the example of University X, if the university has correctly determined that ineligible hESC line research represents 2 percent of total organized research direct costs, then by definition it is appropriate to allocate 2 percent of organized research F&A costs to such research, including 2 percent of the grants administrator's salary.

A less extreme argument that might have been made in the absence of the NIH guidance is that University X must affirmatively "carve out" from its F&A rate calculation the F&A costs specifically associated with ineligible hESC line research. Although University X's overall organized research F&A rate is 60 percent, it is possible that the F&A costs associated with ineligible hESC line research are proportionally higher or lower than 60 percent. For example, if University X were to make a separate F&A allocation to the \$1 million in direct costs of ineligible hESC line research, it might determine that the F&A costs associated with such research are not \$600,000 (which would follow from the application of the 60 percent F&A rate to the \$1 million in direct costs), but \$800,000. If that were the case, then allocating only \$600,000 in F&A costs to the ineligible hESC line research would understate the F&A costs of that research. The \$200,000 in F&A costs of the ineligible hESC line research that were not captured in the \$600,000 effectively would be paid by other organized research projects, including some federal projects—arguably in contravention of the president's prohibition. The only sure way to avoid this result would be to require grantees to "carve out" F&A costs associated with ineligible hESC line research from all other organized research F&A costs.

Again, however, the NIH guidance does not appear to require any such F&A cost carve-out. FAQ 4 makes it clear that each institution is required only to apply its normal negotiated organized research F&A rate to a

⁷ In reality, under OMB Circular A-21 the 26 percent cap on the administrative component of the F&A rate often limits the administrative costs that a university is able to recover through its F&A rate.

base of direct costs of ineligible hESC line research, strictly determined in accordance with the allocation rules of the applicable cost principles.

Regrettably, two statements in the NIH guidance create some potential confusion on this carve-out issue. The first statement, which appears in FAQ 7, is as follows:

"... your university or research center [must have] in place a method of separating the costs of supporting your laboratory so that any of the facilities and administrative (F&A) costs allocable to your new stem cell line work are excluded from the Federal share of the organized research cost base, per the provisions of OMB Circular A-21." [Italics added.]

Read superficially, this reference to "excluding" F&A costs "allocable to your new stem cell line work" sounds like the kind of carve-out of F&A costs that FAQ 4 seems to make unnecessary. Upon closer reading in context, however, this interpretation does not appear to be supportable. For one thing, the language refers to the exclusion of F&A costs not from the university's F&A cost pools (which is what an F&A carve-out would require), but from the "organized research cost base." Because the organized research cost base by definition can include only *direct* costs, it is meaningless to require the exclusion of F&A costs from that base. Although it is ultimately unprofitable and speculative to attempt to reconstruct the meaning of language that is apparently garbled in some way, the best interpretation of the language, read in the context of the other FAQs, is that the "exclusion" of F&A costs is something that will take place automatically, through the normal application of F&A rates to direct costs strictly determined under the cost principles. This interpretation is supported by the last phrase of FAQ 7, which reaffirms that whatever the exclusion might be, it is to be "per the provisions of OMB Circular A-21." Since OMB Circular A-21 does not require a carve-out of F&A costs, it is reasonable to interpret this reference as a reference to the direct cost allocation principles of the circular.

Somewhat more troublesome is the statement in FAQ 8 that:

With respect to indirect costs, also known as facilities and administrative (F&A) costs, institutions engaged in unallowable stem cell work must be able to demonstrate that none of the costs of supporting this work have been included in the rates established and used to charge F&A costs to Federally funded research.

The problem with this language is the phrase "have been included in the rates established and used to charge F&A costs to federally funded research." (Italics added.) The only way to exclude F&A costs related to ineligible hESC research from the organized research rate used to charge F&A costs to federal research is to carve out those costs from the organized research rate calculation. Doing so, however, would be inconsistent with the usual practice under OMB Circular A-21, which is to establish a single institution-wide organized research F&A rate. If it had been the intention of NIH and DCA to require institutions to "carve out" the F&A costs for ineligible hESC research and establish a separate F&A rate for such research, then presumably they would have said so directly in the NIH guidance. Since the NIH guidance contains no such statement, it must be presumed that the language in FAQ 8 does not re-

quire that F&A costs related to ineligible hESC research be routinely carved out of the F&A rate calculation.⁸

There also is a practical consideration that weighs against the F&A carve-out approach. Most major research universities and other research institutions operate on the basis of a series of predetermined F&A rates, which remain in effect for several years. Even if F&A costs specifically allocable to ineligible hESC line research were carved out of the F&A rate calculation process, these predetermined rates would remain in effect (unless they were specifically renegotiated with the government). Consequently, an F&A carve-out would have no effect whatsoever on the F&A costs actually reimbursed by federal sponsors under the agreed-upon predetermined rates.⁹

A better interpretation of the language in FAQ 8 is that it requires each institution to follow the procedures of the applicable OMB circular for determining its organized research F&A rate, on the premise that those procedures, if strictly followed, will themselves ensure that F&A rates applied to federal research do not include F&A costs that should be borne by ineligible hESC line research. This interpretation is consistent with the rest of the NIH guidance, as well as with the principles of OMB Circular A-21 and the other cost principles.

Another aspect of the NIH guidance that merits attention is the suggestion—which appears in two of the FAQs—that institutions must “demonstrate” that no federal funding has been used to support ineligible hESC line research. FAQ 4 states that

A properly documented F&A proposal utilized in the establishment of F&A rates, should demonstrate that none of the costs of unallowable stem cell research or other unallowable activities have been shifted to Federally sponsored activities.

FAQ 8 states that

⁸ There could, however, be extreme circumstances in which a separate F&A rate for ineligible hESC line research would be appropriate. Section G.1.b of OMB Circular A-21 provides that it may be appropriate to create a separate F&A cost pool and base for a certain category of research work if (a) the F&A costs applicable to such work are significantly higher than those associated with other organized research, and (b) the volume of work in the category is material in relation to the volume of other organized research at the institution. These criteria could be met, for example, if an institution were to construct a major new building dedicated solely to ineligible hESC line research. In that case, the F&A costs might be relatively high (because of today’s relatively high construction costs, for example), and the volume of research activity in the building also might be material relative to other organized research. The purpose of such a carve-out would be not to separate ineligible hESC line research costs from other organized research costs, but rather to take appropriate account of the relatively high F&A costs associated with a major new research building. In any case, a separate F&A rate calculation for such activity would require the approval of DHHS’s Division of Cost Allocation; it could not be established unilaterally by the institution.

⁹ F&A rates normally are negotiated prospectively on the basis of historical cost data from a “base” year. For example, cost data from an institution’s 2003 fiscal year might be used as the basis for an F&A proposal submitted and negotiated in fiscal 2004, to set rates for fiscal 2005 through 2007. In this example, an F&A carve-out in fiscal 2005 would not affect the F&A rate for fiscal 2005, which already would be predetermined. Such a carve-out could, however, affect the F&A cost calculation for the next base year (probably fiscal 2006 in this example), which in turn could affect the predetermined rates that are set using the data from the base year.

With respect to indirect costs, also known as facilities and administrative (F&A) costs, institutions engaged in unallowable stem cell work must be able to demonstrate that none of the costs of supporting this work have been included in the rates established and used to charge F&A costs to Federally funded research.

The use of the word “demonstrate” in these two FAQs raises the question of whether grantees involved in ineligible hESC line research are required to present some special additional calculation or explanation in their F&A rate proposals, or in any other document submitted to the federal government. The alternate explanation is that the requirement to demonstrate only requires the grantee to be able to show, if challenged after the fact, that it has strictly complied with the cost allocation rules of OMB Circular A-21 or other applicable cost principles.

The latter interpretation appears more likely, as well as more sensible. With respect to FAQ 4, it is difficult even to imagine what a grantee could say or present in its F&A rate proposal that would demonstrate that no costs of “unallowable” hESC activities have been “shifted to Federally sponsored activities.” A “properly documented” rate proposal presumably would make it clear that the modified total direct costs of all organized research (which would include ineligible hESC line research) have been included in the F&A rate denominator. Doing so would ensure that ineligible hESC line research would bear its fair share of total organized research F&A costs—and more importantly, that federal projects would not bear more than their fair share of such costs. There would be no occasion or opportunity in an F&A rate proposal to explain how *direct* costs are allocated between federal projects and ineligible hESC line projects, and it appears unlikely that NIH or DCA intended to require such an explanation.

The demonstrate language in FAQ 8 does not refer to the F&A rate proposal or any other document, so it appears even less likely in the case of this FAQ that NIH intended to require a specific showing, explanation, or calculation. Under the cost principles, a showing that “none of the costs of supporting this work have been included in the rates established and used to charge F&A costs to Federally funded research” could be made simply by demonstrating that the grantee had strictly complied with the applicable cost allocation principles and with the procedures for applying F&A rates to modified total direct costs. If this is all NIH intended to require, as seems likely, then FAQ 8 represents essentially a confirmation of the core principle of FAQ 4.

The final aspect of the FAQs that requires comment is the repeated reference to ineligible hESC line research as an “unallowable” activity. Such research obviously is unallowable in the lay sense of the word, because the president’s announcement makes clear that agencies will not be allowed to use federal funds to support such research. In the accounting sense, however, the word “unallowable” as applied to an “activity” usually suggests that both the direct costs of the activity and the associated F&A costs should be carved out from the organized research F&A rate calculation. For example, because lobbying is an unallowable activity under the cost principles, those principles require grantees to exclude lobbying activity from both the numerator and the denominator of the F&A rate calculation. As discussed above, that evidently is not what NIH and DCA intended in the case of ineligible hESC line re-

search. On the contrary, it seems obvious that NIH and DCA intended to *require* that ineligible hESC line research be considered part of organized research, and included in the denominator of the F&A rate calculation, so that it would draw its appropriate allocation of the total F&A costs of such research.

In summary, the NIH guidance appears to establish the following principles with considerable clarity:

- Institutions engaged in ineligible hESC line research will be required to comply strictly with the direct cost allocation principles of OMB Circular A-21 (or other applicable principles) in order to ensure that federal projects do not bear any of the direct costs of such hESC research.
- There is no requirement in the NIH guidance that hESC research or that sources of hESC research costs (such as supply storerooms) be physically segregated from federal research activity, if appropriate cost allocations can be made without such segregation.
- If direct costs of ineligible hESC line research are properly allocated to such research, and the normal negotiated F&A rates are properly applied to such allocations, then the F&A costs of hESC research also will be deemed to have been allocated properly, and no federal F&A funds will be deemed to have supported such research.
- There is no requirement to alter the method by which institutions calculate their F&A rates, and specifically no requirement to carve out hESC research from that calculation. (In fact, such a carve-out would not be permitted in most instances, since the cost principles contemplate that the F&A rate normally must apply to all organized research.) Institutions are, however, required to follow the F&A cost allocation procedures of the applicable cost principles, in order to ensure that federal research bears no F&A costs that are properly allocable to ineligible hESC line research.
- There does not appear to be any special reporting requirement with respect to the treatment of the costs of ineligible hESC line research.

5. Special Situations Not Directly Addressed by the NIH Guidance

As helpful as the NIH guidance is, there are a number of questions and situations that it does not directly address. Several of these special situations are identified and discussed briefly below; there undoubtedly are others. In the absence of government guidance regarding these situations, the best an institution can do is to adopt a conservative and common-sense approach, document it, and follow it as consistently as possible.

Real property acquired in whole or in part under federal awards. Normally a federal grantee recovers the costs of real property only through the depreciation costs that are included in the grantee's F&A rate calculation. As discussed above, the fact that such property costs are reimbursed in part by federal F&A payments does not in itself prohibit the grantee from conducting ineligible hESC line research in such property, if the property has not been directly funded by a federal agency. In some cases, however, a federal award will directly support costs associated with real property—typically the acquisition, construction, or renovation of a building. In these cases, the cost of the real property is a direct charge to the federal award. Although normally title to such real property vests in the grantee, un-

der OMB Circular A-110 the government retains the right to approve or disapprove the use of the property for purposes other than the federal project or projects for which the property was first acquired. OMB Circular A-110, § __.32. It is reasonable to assume that the federal government would not approve the use of property acquired with federal funds for ineligible hESC line research, and in the absence of such approval any institution engaged in such research should take steps to ensure that the research is not conducted in a building acquired, constructed, or improved under a federal award.

There may be other situations in which the government's response will be less predictable. For example, if direct federal funding has supported the renovation of one floor of a building, it is by no means clear that the president's prohibition would preclude an institution from carrying out ineligible hESC line research on another floor of the same building. Even in such a case, however, it would be advisable to seek government approval, or at least notify the government of the intended use.

Capital equipment acquired under a federal award. As in the case of real property, normally a grantee recovers its capital equipment costs through depreciation charges that are included in the grantee's F&A rate calculation. It is not uncommon, however, for a federal sponsor to approve the acquisition of capital equipment under a federal grant, in which case the full acquisition cost is directly charged to the grant. In such cases, the grantee normally takes title to the equipment, but as in the case of real property acquired under federal awards, OMB Circular A-110 imposes certain restrictions on the use and disposition of such equipment. OMB Circular A-110, § __.34. For example, a grantee may not use equipment acquired with federal funds to provide services to non-federal organizations for a fee that is less than private organizations charge for equivalent services. In light of the various rights that the federal government continues to assert throughout the useful life of any capital equipment subject to OMB Circular A-110, it is likely that the government would consider the use of such equipment by an ineligible hESC line project to be an indirect use of federal funds.

It is important to note, however, that under 31 U.S.C. § 6306 agency heads "may vest title in tangible personal property in a nonprofit institution of higher education or in a nonprofit organization whose primary purpose is conducting scientific research . . . without further obligation to the United States Government." NIH routinely exercises this authority in its grant awards, with the result that equipment purchased under such grants becomes "exempt property" that is not subject to most of the post-acquisition restrictions of OMB Circular A-110.¹⁰ An argument could be made that because the grantee acquires title to exempt property "without further obligation to the United States Government," such property may be used for any purpose, including even ineligible hESC line research. As always, however, in-

¹⁰ "For equipment and supplies purchased under NIH grants for basic or applied research by non-profit institutions of higher education or non-profit organizations whose principal purpose is the conduct of scientific research, the grantee is exempt from any requirement to account to NIH for proceeds from the sale of the equipment or supplies. . . ." NIH Grants Policy Statement, p. 122 (December 2003). See also p. 125, "Exempt Property."

stitutions should use common sense in relying on such an argument. For example, if a grantee were to purchase a major item of “exempt” equipment with NIH funds and immediately thereafter dedicate the equipment to use in ineligible hESC line research, the grantee would be inviting unwelcome scrutiny against which technical legal arguments might provide little protection. On the other end of the spectrum, a grantee might well be able to defend such use of exempt equipment after the expiration of the NIH grant that financed its purchase.

In short, institutions engaged in ineligible hESC line research should proceed with care in connection with any use of federally funded equipment in such research. Although it may be possible to defend such use of equipment purchased with NIH funds, any significant use of such equipment should be scrutinized on a case-by-case basis to avoid problems of perception as well as legal problems.

Federal subsidization of institutional activity. NIH and some other federal sponsors often provide funding to a research institution to support the institution’s research infrastructure. For example, an NIH Research Core Center (P30) award is an award made to support centralized resources and facilities used or shared by investigators throughout the institution, or in a particular research area (such as a DNA facility). Any institutional research project that makes use of an NIH-supported centralized resource or facility potentially is an indirect recipient or beneficiary of the federal funding provided to that resource or facility. (For example, the internal institutional user fee for use of the resource or facility may be reduced because of the NIH support.) To the extent that any ineligible hESC line research project makes use of an institutional resource or facility that has been supported by federal funds, it would be advisable to take reasonable steps to ensure that the project does not benefit from such federal support.

NIH-funded biomedical research resources. NIH encourages its grantees to engage in wide dissemination of NIH-funded biomedical research materials and resources. It is unclear whether making such materials or resources available to a project involving ineligible hESC line research would be deemed an indirect use of federal funds by that project. If so, then (a) any institution engaged in ineligible hESC line research should avoid use of such materials and resources in such research, and (b) any institution involved in the dissemination of such materials and resources, whether or not it is engaged in stem cell research itself, should take reasonable steps to guard against use of the disseminated items in an ineligible hESC line project.

Projects involving both eligible and ineligible hESC lines. It is possible that a single research project could make use of both eligible and ineligible hESC lines. If the costs of such a project are commingled within a single account in the grantee’s cost accounting system, it may be difficult if not impossible to allocate such costs between permitted and prohibited uses. The conservative and probably the preferable approach in such instances, therefore, would be to treat the entire project as ineligible for federal support. At a minimum, in such cases there should be a clear written methodology, approved by the federal sponsor, for maintaining a strict allocation of costs between the eligible and ineligible hESC line work.

Ineligible hESC lines received from others. When acquiring ineligible hESC lines from another entity, it will be advisable for research institutions to seek contractual assurances from the provider that no federal funds have been used in the development of the lines. A receiving institution should be entitled to rely on such an assurance in the absence of any specific reason to believe that it is not accurate.

6. Recommendations

In light of the foregoing, any institution engaged in ineligible hESC line research that also receives federal research funding should consider the following recommendations:

Develop an institutional policy summarizing what steps must be taken to prevent federal funds from being used to support ineligible hESC line research. Such a policy need not be a long document; its principal purpose is to demonstrate that the institution has attempted in good faith to comply with the president’s federal funding prohibition. It also can serve as a basic reference that investigators and other personnel can turn to in order to understand the institution’s general policy on the subject.

Provide special written protocols on cost allocation to investigators engaged in ineligible hESC line research. As noted above, FAQ 6 of the NIH guidance states that institutions should provide “clear instructions” to investigators concerning the proper allocation of costs to ineligible hESC line projects. Experience shows that investigators and administrators are sometimes careless in allocating costs to projects, and such carelessness in this context could have serious consequences. Even if the FAQs did not call for “clear instructions,” therefore, any institution engaged in ineligible hESC line research would be well advised to provide such instructions in the form of a written protocol tailored to each such project. In addition, institutions should provide specific training to investigators and administrators to emphasize the importance of following the written cost allocation protocol.

Designate an administrator with federal cost accounting expertise to monitor the expenditures of ineligible hESC line projects, in order to confirm that the cost allocation instructions are understood and are being followed. Given the difficulty that investigators and administrators sometimes have with cost allocation issues even in ordinary circumstances, there is no reason to take it for granted that they will be able on their own to achieve the “strict” compliance with the cost allocation rules that the NIH guidance contemplates. It is recommended, therefore, that at least at the beginning of any project involving ineligible hESC line research, a knowledgeable financial administrator be assigned to monitor compliance. Whether it is necessary to continue such monitoring beyond the initial stages of a project can be determined based on the experience with each project team.

Before allowing an ineligible hESC line project to use real property, equipment, or resources developed with federal funds, investigate the circumstances and seek federal sponsor approval if necessary. The NIH guidance is silent on the subject of whether use of such property, equipment, or resources constitutes a prohibited use of federal funds. However, where the federal government asserts a continuing interest in such property based on its having been acquired or produced

with federal funds, the prudent approach appears to be to preclude use of such property in ineligible hESC line research. A more liberal approach may be defensible in the case of “exempt property” purchased with NIH funds, but even here grantees should exercise careful judgment. Even in situations where use of federally financed property or resources appears to be defensible, it nevertheless may be prudent in some cases to obtain specific government approval of such use.

Remain sensitive to appearances as well as cost accounting technicalities; if a situation does not “feel” right, even if it is defensible under the NIH guidance, subject it to special scrutiny. Institutions should understand that the NIH guidance is based on an accounting theory whose logic is not necessarily intuitively obvious to government officials, politicians, and members of the

public. There may be cases in which a cost allocation that is justifiable from an accounting standpoint has every appearance, to a nonaccountant, of a prohibited use of federal funds. There is no guarantee that accounting theory always will prevail in such cases; institutions therefore should use common sense as well as accounting principles in dealing with these situations.

Be alert for shifts in federal policy on the funding issue. The NIH guidance interpreting the bar on use of federal funding in ineligible hESC line research is still relatively new and untested, and political sensitivities make the entire subject of hESC research inherently volatile. All institutions engaged in such research, therefore, should remain attuned to the possibility of shifts in policy in this area, and be prepared to adjust their own policies and practices accordingly.