

**Department of Health and Human Services  
DEPARTMENTAL APPEALS BOARD  
Appellate Division**

FFA Sciences, LLC  
Docket No. A-11-113  
Decision No. 2476  
September 25, 2012

**DECISION**

FFA Sciences, LLC (FFA Sciences) appealed a decision by the National Institutes of Health (NIH) Appeals Board pursuant to the informal appeals process at 42 C.F.R. Part 50, subpart D. The NIH Appeals Board upheld a determination by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). NIDDK had disallowed the entire amount of an NIDDK grant award and withheld future funding for the grant project on the basis that FFA Sciences had materially failed to comply with the terms of the award. The NIH Appeals Board found that NIDDK had a legitimate reason for requesting information from FFA Sciences to justify its accelerated drawdown of cash under the award and that FFA Sciences did not provide such information, despite repeated contacts and letters from NIDDK requesting a site visit and information and documentation.

For the reasons stated below, we conclude that FFA Sciences materially failed to comply with the terms and conditions of its NIDDK award. FFA Sciences repeatedly failed to give NIDDK access to financial and scientific records in the face of legitimate concerns about the accelerated rate at which FFA Sciences drew down federal funds in relation to the reported scientific progress, and then did not timely submit information and documents NIDDK requested to address its concerns. We therefore uphold the NIH determination to withhold further funding for the project. We also uphold NIH's determination to disallow \$597,219 because we further conclude that disallowance of the full amount awarded to FFA Sciences is authorized and justified under the circumstances here. In light of FFA Sciences' noncompliance, NIH had no assurance that any costs were properly charged to the NIDDK award. Moreover, while FFA Sciences belatedly submitted the requested documents to us, that action neither cured the noncompliance nor provided adequate assurance that any of the funds were properly spent given the circumstances here, including FFA Sciences' disingenuous attempts to obfuscate the issues and its failure, even now, to account for the accelerated rate at which it drew down federal funds.

## Legal Background

A grant award is a type of federal financial assistance that provides support or stimulation to accomplish a public purpose. 45 C.F.R. §§ 74.1, 74.11; 31 U.S.C. 6301-08. Research grant awards made by the NIH, or one of its institutes, such as NIDDK, are subject to general terms and conditions depending on the type of grantee and other factors, as well as any special terms and conditions in the notice of grant award. NIH issues a Grants Policy Statement to consolidate requirements into one document written in plain English. The version applicable here is the statement issued in 2003, and we refer to it as the NIHGPS.

Any grant award by the Department of Health and Human Services (HHS) to a for-profit grantee (also referred to as a commercial organization) is also subject to the administrative requirements in 45 C.F.R. Part 74. 45 C.F.R. § 74.1. Recipients must, among other things, meet the standards set out in Part 74 for financial management systems and for making payments under an award. Among other things, a recipient's financial management system must provide for the following:

- (1) Accurate, current and complete disclosure of the financial results of each HHS-sponsored project or program . . . .
- (2) Records that identify adequately the source and application of funds for HHS-sponsored activities [including] information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, outlays, income and interest.
- (3) Written procedures to minimize the time elapsing between the transfer of funds to the recipient from the U.S. Treasury and the issuance or redemption of checks, warrants or payments by other means for program purposes by the recipient. . . . .
- (4) Accounting records, including cost accounting records, that are supported by source documentation.

45 C.F.R. § 74.21.

A recipient must retain financial records, supporting documents, and all other records pertinent to an award for a specified period. 45 C.F.R. § 74.53(a). HHS awarding agencies or any of their duly authorized representatives “have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards . . . .” 45 C.F.R. § 74.53(e). HHS may also make site visits as needed to monitor award performance. 45 C.F.R. § 74.51(e).

Recipients of NIH awards who receive electronic payments through the HHS Payment Management System (PMS) must submit a quarterly cash transaction report, referred to as PSC-272 or SF-272. NIHGPS, at 131.<sup>1</sup> Cash advances to a recipient “shall be limited to the minimum amounts needed and be timed to be in accordance with the actual, immediate cash requirements of the recipient organization in carrying out the purpose of the approved program or project” and the “timing and amount of cash advances shall be as close as is administratively feasible to the actual disbursements by the recipient organization for direct program or project costs and the proportionate share of any allowable indirect costs.” 45 C.F.R. § 74.22(b)(2); 31 C.F.R. Part 205. As the NIHGPS explains, “the intent is that grantees draw funds on an as-needed basis—specifically, no more than 3 days before the funds are needed” and “funds deposited by PMS in a grantee’s bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds.” NIHGPS at 76.

Recipients are not required to have separate depository accounts, but “must be able to account for the receipt, obligation and expenditure of funds.” 45 C.F.R. § 74.22(i)(1). With certain exceptions not relevant here, recipients must “maintain advances of Federal funds in interest bearing accounts” and remit any interest in excess of \$250 to HHS.” 45 C.F.R. §§ 74.22(k), (l); NIHGPS at 78.

“Where a funding period is specified, a recipient may charge to the award only allowable costs resulting from obligations incurred during the funding period and any pre-award costs authorized by the HHS awarding agency ....” 45 C.F.R. § 74.28. Under the system of funding that NIH uses, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods. NIHGPS at 73-75. An initial Notice of Grant Award (NGA) issued by NIH obligates federal funds for the project during the first budget period (usually 12 months long). That NGA also documents approval of a project period (usually three to five years) and anticipated levels of future support. The NIHGPS explains, however, that approval of the project period merely “expresses NIH’s intention to provide continued financial support for the project” and creates “no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NGA,” since future support is “contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government.” NIHGPS at 75, 137. Approval of the project period means, however, that the recipient of the initial award may apply for a non-competing continuation award for future funding within the project period, rather than having to compete with other applications for funding.

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<sup>1</sup> Page cites are to the PDF version of the NIHGPS currently available at [http://grants.nih.gov/grants/policy/nihgps\\_2003](http://grants.nih.gov/grants/policy/nihgps_2003).

As a prerequisite to NIH approval of a non-competing continuation award, a grantee must submit an annual progress report. A streamlined process (called SNAP) permits some grantees to submit a more abbreviated progress report and to forego submitting an annual financial status report. The NIHGPS warns, however, that the Grants Management Officer may “require additional information to evaluate the project for continued funding” and may use the cash transaction reports submitted to PMS to monitor the grant, reviewing patterns of cash expenditures, including accelerated or delayed drawdowns, to assess whether programmatic or financial management problems exist. NIHGPS at 131-132.<sup>2</sup> Elsewhere, the NIHGPS informs grantees that NIH “expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations.” *Id.* at 84. The NIHGPS explains that “[e]xpenditure patterns are of particular concern because they may indicate a deficiency in the grantee’s financial management system or internal controls” and “[a]ccelerated or delayed expenditures may result in a grantee’s inability to complete the approved project within the approved budget and period of performance.” *Id.* In these situations, the Grants Management Officer “may seek additional information from the grantee and may make any necessary and appropriate adjustments.” *Id.*

Part 74 provides that the allowability of costs incurred under a grant by commercial organizations is “determined in accordance with the provisions of the Federal Acquisition Regulation (FAR) at 48 CFR part 31, except that independent research and development costs are unallowable.” 45 C.F.R. § 74.27(a); *see also* § 74.27(b)(2). The cost principles distinguish direct costs (that are readily identifiable with a specific cost objective, such as a grant project) and indirect costs (that cannot be so identified, but nonetheless benefit the cost objective). NIHGPS at 81-82; 48 C.F.R. §§ 31.201-31.203. In the research context, indirect costs are referred to as Facilities & Administrative (F&A) costs. To charge indirect costs to a federal grant, the grantee must have an approved indirect cost rate. NIHGPS at 81. NIH uses the most recently approved rate to calculate indirect costs for the initial award for an approved project and anticipated future support.

Where a recipient has “materially failed to comply with the terms and conditions of an award,” the awarding agency may “take one or more” enforcement action, including terminating an award, withholding further awards for a project, or disallowing “all or part of the cost of the activity or action not in compliance.” 45 C.F.R. § 74.62(a). This regulatory provision is basically repeated in Part II of the NIHGPS. Elsewhere, the NIHGPS states that “Part II of the NIHGPS includes administrative and other remedies the Federal government may use if a grantee deliberately withholds information or submits fraudulent information or does not comply with applicable requirements.”

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<sup>2</sup> For each award, NIH appoints a Grants Management Specialist, who is responsible for the negotiation, award, and administration of the project and for interpretation of grants administration policies and provisions, and a Program Official, who is responsible for the scientific, programmatic and technical aspects of the project. AF Ex. 1, Att. D. Certain actions may be taken only by the Grants Management Officer, however. NIHGPS at 10, 17.

NIHGPS at 24. It then lists other authorized civil or criminal actions and states that “NIH also may administratively recover misspent grant funds pursuant to the authorities contained in 45 CFR Parts 74 and 92.” *Id.* at 25. Part II also distinguishes enforcement actions from recovery of “funds paid to a grantee in excess of the amount to which the grantee is finally determined to be entitled under the terms and conditions of the award, including misspent funds or unallowable costs incurred.” *Id.* at 137-138.

## **Factual Background**

The facts set out below are either undisputed or supported by the contemporaneous documents in the record. FFA Sciences is a small biotech company that, among other things, does research on non-alcoholic fatty liver disease (NAFLD), with the goal of developing and using protein probes to diagnose and stage the progress of the disease by measuring unbound free fatty acids. FFA Sciences applied for serum samples from individuals with NAFLD from the Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN), a research group funded by NIDDK. In 2006, FFA Sciences received 38 serum samples and then, in 2007, received 100 serum samples plus an indication that NASH CRN might release more samples later.

NIDDK issued a program announcement seeking “ancillary studies” to major clinical research studies, including NASH CRN. In June 2007, based in part on a letter of support from NASH CRN indicating it had approved giving FFA Sciences 100 samples, FFA Sciences applied for a competing award under NIDDK’s program announcement. NIDDK notified FFA Sciences that this grant application was not funded and why. In March 2008, FFA Sciences resubmitted an application, responding to some of the criticisms of its first application and relying on the same letter of support from NASH CRN. This application set out four grant aims, with the proposal requesting 1500 samples from NASH CRN in order to achieve those aims.

In May 2008, a member of the NASH CRN publications committee informed FFA Sciences that the committee had disapproved FFA Sciences’ abstract on research it conducted using the NAFLD samples it had already received. AF Ex. 1, Att. B.

NIDDK issued an NGA dated February 13, 2009, that—

- Awarded \$541,230 for the budget period February 13, 2009 through November 30, 2009;
- Approved a project period of February 13, 2009 through November 30, 2012, with recommended future support “subject to the availability of funds and satisfactory progress of the project”;
- Permitted allowable pre-award costs to be charged to the award in accordance with the conditions outlined in the NIHGPS, subject to prior approval if incurred more than 90 days before February 13, 2009;

- Included funds for “consortium activity” with two co-investigators from the University of California, San Diego (to cover both direct and F&A costs of those activities);
- Calculated indirect costs at a 106% rate, applied to a direct cost base that excluded the amount budgeted for “consortium/contracts.”

AF Ex. 1, Att. D. The notice stated that, “to meet current NIDDK objectives and based on the relative scientific merit ranking of this application, the budget for the initial period has been programmatically reduced.” *Id.* (2/13/09 NGA at 4). The revised NGA issued on September 29, 2009, provided supplementary funds of \$55,989 for the initial budget period “to adjust for the appropriate NIDDK programmatic reductions . . . .” *Id.* (9/29/09 NGA at 4).

By March 31, 2009, FFA Sciences had drawn down, through the HHS Payment Management System (PMS), \$450,000 of the initial \$541,230 awarded (that is, over 83% of the amount awarded).

FFA Sciences was notified in July 2009 that NASH CRN had disapproved its request for more samples. In October 2009, FFA Sciences applied to NIDDK for a non-competing continuation award, indicating that 328 samples were “available” from NASH CRN and reporting some progress on three of the four project aims, but no progress on one aim. In that same month, NASH CRN again denied FFA Sciences’ request for further serum samples. (FFA Sciences did not appeal this denial until February 13, 2010, and its appeal was rejected on February 15, 2010. AF Ex. 4, at 2.)

FFA Sciences inquired about the status of the continuation award in January 2010 (after, it says, it had previously been told the continuation award would be made when funds were available). In a January 6, 2010 response, Dr. Edward Doo, the NIDDK Director of Liver Disease Research Programs and the Program Officer for the award, inquired how FFA Sciences intended to pursue the project, given the unavailability of samples from NASH CRN and the essential nature of those specimens for the conduct of the project. NIH Ex. 5, at 23; AF Ex. 8, Att.C, at 5. This led to various communications between Dr. Alan Kleinfeld, FFA Sciences’ owner and Principal Investigator, and NIDDK, including a telephone conversation on March 10, 2010 (discussed below) with Dr. Doo and Dr. Patricia Robuck, an NIDDK official who was also affiliated with NASH CRN, and to a March 14, 2010 letter from Dr. Kleinfeld to NIDDK’s Director of Extramural Activities. AF Ex. 1, Atts. G, H, I.

In a **March 31, 2010** letter signed by Dr. Doo and a Senior Grants Management Specialist, NIDDK reviewed the chronology of interactions between FFA Sciences and NASH CRN, the aims of the NIDDK grant, and the progress report submitted with the continuation application (which NIDDK said demonstrated “modest incremental advances” on the grant aims). NIH Ex. 6, at 4-6. The letter stated that “[c]larification is

needed on the availability of serum samples from NASH CRN as stated in Section D [of the progress report] in relation to your acknowledgement of denial of additional samples . . .” *Id.* at 6. In addition, the letter stated:

The NIDDK Grants Management Staff has completed a financial review of expenditures for this grant per reports provided by the [PMS]. The [PMS] provides us with amounts that are reflected on the PSC 272 report as cumulative total expenditures. This report showed the following for cumulative expenditures:

Report dated March 31, 2009	\$450,000
Report dated June 30, 2009	\$ 91,230
Report dated December 31, 2009	<u>\$ 55,000</u>
Total	\$597,219

Please provide internal corporate account statements that **detail the expenditures for the above listed totals**. In addition, please provide documentation of your institutional policy on administering the expenditure of federal research funds.

*Id.* at 6-7 (emphasis added).

With its response letter dated **April 12, 2010**, FFA Sciences submitted a one-page internal corporate account statement listing accrued expenses for the grant in general categories for the entire period November 13, 2008 through December 31, 2009. FFA Sciences also submitted an undated Policies and Procedures Manual. Among other things, this Manual addresses drawdowns from the PMS, indicating that FFA Sciences understood the need to minimize the time between drawdown of federal cash and outlays for project expenses. Yet, nowhere in the letter does FFA Sciences seek to respond to the questions raised by the fact it had drawn down most of the initial award by March 31 and had drawn down all the funds from the initial award by June 30, five months before the end of the budget period (November 30, 2009).

A **May 10, 2010** letter to FFA Sciences from Dr. Doo and NIDDK’s Chief Grants Management Officer said that, after further review, NIDDK staff “would like to arrange a site visit to seek further clarification of the scientific progress and to review the administrative and financial policies used to manage” the grant. NIH Ex. 8, at 6. They proposed to conduct the site visit on June 3, 2010 and asked FFA Sciences to complete an enclosed Organizational System Review Questionnaire by May 26 and to be prepared to discuss the answers to the questions with the site visit team. *Id.*

In a May 13, 2010 email, FFA Sciences inquired whether “the proposed site visit is done for all grantees.” NIH Ex. 8, at 36. NIDDK replied on May 17, stating in pertinent part:

Site visits are performed from time to time to various grantees in order to clarify issues regarding scientific progress as well as budgetary and financial procedures. We are very concerned about the progress reported [and] have **noticed significant draw downs . . . and need to seek clarification on these expenditures. . . .** please let us know if June 3, 2010 is an acceptable date for us to conduct our site visit.

*Id.* (emphasis added). FFA Sciences’ response of May 20 repeated the statement of NIDDK’s concerns, but referred back to the telephone conference of March 10 which discussed the 2008 abstract disapproved by NASH CRN, suggesting that the focus should be on issues regarding the data for the abstract and that the visit should occur between July 7 and 30. *Id.* at 38. NIDDK’s May 24 response said that the focus would be the collection of information related to the budgetary expenditure of the grant in relation to the reported scientific progress. *Id.* NIDDK asked for availability for the weeks of July 12 through 23, 2010.

In a June 1 follow-up email, NIDDK reminded FFA Sciences that NIDDK needed to ascertain availability for a site visit. FFA Sciences’ June 2 response did not respond with a date for the visit, instead insisting that the data issue “must be addressed.” *Id.* at 40. The June 4 reply from NIDDK reiterated NIDDK’s intent for the site visit and asked FFA Sciences to let NIDDK know by June 7, 2010 a date for the site visit between July 12 and 23. *Id.* at 43. When FFA Sciences did not respond by the deadline, NIDDK sent an additional email on June 9, saying “we would appreciate a response to our inquiry below by COB today.” *Id.*

FFA Sciences does not claim that it ever responded to this inquiry or to the questionnaire that NIDDK sent with the May 10, 2010 letter.<sup>3</sup> Instead, on **August 11, 2010**, FFA Sciences sent a letter to the Directors of NIH and NIDDK, questioning the actions of NIDDK officials, and suggesting that they were in retaliation for FFA Sciences’ letter of March 14, 2010. NIH Ex. 9. Among other things, FFA Sciences said that it had not been informed of an adverse determination and given its appeal rights, and asked for an independent review of the issues. The NIDDK Director of Extramural Activities was asked to respond and informed FFA Sciences in a letter of September 9, 2010 that he had reviewed the actions of NIDDK staff and determined that NIDDK is “appropriately responding to both scientific and financial concerns . . . .” *Id.* at 4. He clarified that no

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<sup>3</sup> FFA Sciences suggests in an unsigned statement that it viewed the information sought in the questionnaire as “duplicative” of the information in the Policies and Procedures Manual it had already submitted. AF Ex. 8, Att. C, at 3. The questionnaire, however, asked for some information not given in the manual, such as FFA Sciences’ practices with respect to time and effort reporting. Compare NIH Ex. 8, at 9-31 with NIH Ex. 7, at 3-39; see also NIHGPS at 98 (requirement that a for-profit grantee keep records of actual time spent on grant and other activities).

adverse action had been taken but that “until both scientific and financial concerns have been adequately addressed, NIDDK will continue to delay funding of the 02 year.” *Id.* In a **September 21, 2010** letter, NIDDK requested information to “address our concerns about the accelerated rate at which grant funds have been expended and the apparent lack of scientific progress on the grant.” NIH Ex. 10. This letter reviewed again what the PMS records showed and quoted the NIHGPS provisions about the inquiry that might be triggered if a grantee incurred expenditures at an accelerated rate and the intent that grantees draw funds only on an as-needed basis. The letter indicated that the accelerated rate of expenditure not only raised concerns about management of the award but also raised “important questions about how such management may relate to the scientific progress of the project.” *Id.* at 1. The letter reviewed NIDDK’s concerns about scientific progress, noting specifically that “all NASH CRN samples (138 in total) utilized in the year one progress report were at [FFA Sciences’] laboratory by June 22, 2007” (i.e., well before NIDDK made the grant award). *Id.* at 2. The letter also noted that the collaboration between FFA Sciences and NASH CRN “was terminated on February 15, 2009 which severed further access to highly characterized NASH CRN serum samples.” *Id.* This letter referred to the progress report as demonstrating “modest scientific progress at best.” *Id.*

NIDDK’s September 21 letter then reviewed the requests NIDDK had made for information and its six attempts to arrange a site visit. The letter noted that continued funding was contingent on satisfactory scientific progress and that further funding would not be considered until the issues raised in the letter were addressed. NIDDK asked FFA Sciences to provide “from original accounting and administrative records copies of the following documents (preferably in electronic format) for the time period from February 13, 2009 through November 30, 2009”:

1. Expenditure reports (monthly, or in alignment with your accounting cycle) showing detailed breakdowns of direct costs (i.e., supplies, equipment, travel, consultants, etc.) and associated facilities and administrative (F&A) costs charged to the grant. Please provide supporting documentation and a statement indicating the relevance of each expenditure to the grant. Please also include the same documentation for any pre-award costs charged to the grant.
2. An accounting of the salaries and fringe benefits for all employees charged to the grant. Please include each employee’s title, role, and responsibilities on the grant.
3. Time and Effort Reports for all employees charged to the grant. Please include a brief summary of the work performed by each employee during each accounting cycle

4. Please provide an accounting of all new data generated during the period of time indicated in your annual progress report for each specific aim. Also, please indicate which investigators named on this grant contributed effort in the analysis of the data generated for each specific aim.

NIH Ex. 10, at 2-3.

The September 21 letter asked that FFA Sciences submit its response **by October 15, 2010**, and warned that “[f]ailure to provide complete and timely information may cause NIH to take one or more enforcement actions in accordance with 45 CFR 74.62 . . . .” *Id.* at 3.

On **October 25, 2010**, NIDDK’s Chief Grants Management Officer, sent an email to FFA Sciences noting that NIDDK had not yet received a response to its September 21 letter, reminding FFA Sciences of the possibility of an enforcement action, and asking for the information “no later than October 27, 2010.” NIH Ex. 12, at 1.

FFA Sciences apparently acknowledged the request in an email dated October 31, 2010. NIH Ex. 13, at 1. In a **December 20, 2010** letter, however, NIDDK said (and FFA Sciences does not deny) that the email did “not respond to the four specific requests . . . that required a written response by October 15, 2010 in addition to a confirmed date for a site visit.” *Id.* The letter emphasized that NIDDK’s “prompt receipt of that information is critical to our oversight responsibilities” and that, if NIDDK did not receive the information by December 28, 2010, it would “pursue enforcement action(s).” *Id.* (emphasis in original). This letter also addressed what it called “misunderstandings” in the October 31 email from FFA Sciences and expressed regret that Dr. Doo’s statement in a March 10, 2010 email that “administrative termination” would commence might have contributed to that misunderstanding. The letter noted that “we have not terminated nor suspended this grant to date, though we have notified you . . . that we are not considering further funding of the non-competing continuation of the 02 year of this grant until programmatic, financial, and administrative issues raised in our previous letter are addressed to NIDDK’s satisfaction” and had made clear that enforcement actions may be justified. *Id.* at 1-2. This letter also rejected an allegation in the October 31 email that NIDDK’s concerns were “retaliatory,” reviewed why NIDDK was concerned about the PSC-272 cash transaction reports and why the April 12 response was inadequate, and stated how NIDDK had responded to FFA Sciences’ concerns.

FFA Sciences does not deny that it did not respond to this letter. By letter dated **January 24, 2011**, NIDDK notified FFA Sciences that it was taking the following enforcement actions because of FFA Sciences’ material failure to comply with the terms and conditions of the award: (1) disallowing \$597,219 (the entire amount awarded for the first budget period) and (2) withholding support of the non-competing continuation and all further awards for the project. NIH Ex. 14.

By letter dated February 23, 2011, FFA Sciences appealed NIDDK's determination to the NIH Grant Appeals Board. AF Ex. 1. During the course of that appeal, FFA Sciences was given an opportunity to submit any information and documentation to address the concerns NIDDK had previously raised. AF Ex. 9. FFA Sciences did not, however, submit any of the documents requested in the September 21, 2010 letter or otherwise address NIDDK's concern about the accelerated rate of drawdowns. Instead, FFA Sciences relied on various arguments it also raises before us and which we address below.

The NIH Appeals Board upheld NIDDK's determination, finding that NIDDK had appropriately requested scientific and financial information from FFA Sciences in the March 31, 2010 letter, given questions about scientific progress on the project and the accelerated rate of expenditures under the award. The NIH Appeals Board noted that NIDDK then made "multiple requests for a site visit and detailed information," finding that at no time did FFA Sciences provide "any documentation that would justify" the accelerated rate of expenditures." NIH Ex. 1, at 4. The NIH Appeals Board concluded: "In failing to provide the specific financial information requested by NIDDK, FFA Sciences materially failed to comply with the terms and conditions of award . . . ." *Id.* The NIH Appeals Board decision cited to "cost principles" and to the part of the NIHGPS notifying grantees that an accelerated rate of expenditures might lead the grantor agency to request information. *Id.* at 3-4.

FFA Sciences then appealed to this Board. In response to the Board's acknowledgment letter, NIH clarified that the appealed decision was referring to the cost principles in the FAR (that apply to commercial organizations) and that NIH is also relying on the Financial Management System Standards in 45 C.F.R. § 74.21(b). NIH also cited to section 74.62(a) regarding enforcement actions available for material failure to comply with the terms and conditions of an award.<sup>4</sup>

In response to FFA Sciences' informal discovery request and request that NIH agree to alternative dispute resolution (ADR), NIH counsel indicated in a November 14, 2011 letter that if FFA Sciences sent NIH "documentation to support \$597,219 in charges by December 6, 2011," NIH would review the information and that it would assess again the possibility of ADR. In a November 22, 2011 conference call, the Presiding Board Member asked NIH to clarify what documents it meant it would review if submitted by December 6. NIH clarified that it meant the documents requested in NIDDK's September 21, 2010 letter. FFA Sciences' counsel indicated they needed to consult with their client about whether FFA Sciences would commit to submit that documentation

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<sup>4</sup> In its brief, NIH also cited to section 74.53(e) regarding the agency's right to "timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the award" and to the payment requirement in section 74.22(i)(1) that recipients "must be able to account for the receipt, obligation, and expenditure of funds." NIH also submitted as its Exhibit 15 excerpts from the NIHGPS, including the above quote about accelerated drawdowns and other terms and conditions.

and, if so, by when. The parties agreed to get back to the Board on whether FFA Sciences would submit that documentation and the schedule for production. The Board set tentative procedures to apply if FFA Sciences agreed to produce the requested documents by December 6, 2011 or some later date to which NIH agreed. On December 3, 2011, the Board's staff attorney assigned to the case sent an e-mail to the parties since the Board had not heard back from them. Both parties' responses indicated that the parties were engaged in settlement negotiations. Thus, the Board stayed the case and later extended the stay when the parties reported that they had worked out "an initial agreement regarding documents," that FFA Sciences had submitted some documents that NIH was reviewing, and they were still engaged in settlement negotiations. Parties' submission of 1/17/2012.

The settlement negotiations broke down, however. The parties informed the Board Staff Attorney in a March 2, 2012 telephone call that they had been unable to settle the dispute and that the Board should set further procedures.<sup>5</sup> Bd. ltr. of 3/7/2012. The Board then set further procedures asking NIH to first issue its "determination on whether FFA Sciences' documentation is acceptable to document the allowability of the costs charged to the grant, in whole or in part, and, if not, why not." *Id.* NIH responded on March 14, 2012, stating that the parties "were unable to agree on the information to be provided by FFA Sciences that would be reasonably sufficient to permit NIH to assess the allowability" of FFA Sciences' expenditures under the NIDDK award. Subsequently, FFA Sciences submitted its appeal file (AF) to the Board, including documents it said it had submitted to NIH during settlement negotiations and after the negotiations broke down. NIH responded and FFA Sciences replied. The Board also granted each party's request to make a further submission regarding what occurred during settlement discussions, while warning them that this did not mean the Board considered what occurred to be relevant to its decisionmaking.

## **Analysis**

### ***FFA Sciences failed to comply with the terms and conditions of the award for the initial budget period of its NIDDK project.***

FFA Sciences asserts that it was "in compliance with all material terms and conditions of the [NIDDK] grant." FFA Br. at 2. The regulations and NGA required FFA Sciences to comply with **all** terms and conditions of the award, however. The issue under the regulations is whether FFA Sciences' **failure to comply** with the terms and conditions was material.

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<sup>5</sup> The parties indicated that they disagreed over whether to disclose what occurred during settlement negotiations. The Board noted in its March 7, 2012 letter setting further procedures that "it is unnecessary and inappropriate for the parties to describe the content of their settlement negotiations to the Board unless they both determine it would help the Board resolve the case." FFA Sciences nonetheless made representations about the content of the negotiations. NIH objected and submitted its version of what occurred in its Surreply.

FFA Sciences does not deny that the terms and conditions of the grant award required, among other things, that NIDDK be given access to FFA Sciences' grant-related records, including the right to make a site visit to monitor the award, and that NIDDK had the right to seek information, if, among other things, the cash transaction reports for the award showed an accelerated rate of drawdowns of federal cash under the award. Yet, FFA Sciences does not contend that it that it ever gave NIDDK a specific date for a site visit, as requested numerous times, or that it had submitted to NIDDK the specific information and documentation NIDDK requested in the September 21, 2010 letter within the deadline set, even though NIDDK extended the deadline twice, until the end of December.

FFA Sciences asserts only that it submitted "sufficient information" to NIDDK when it submitted the one-page account statement and its Policies and Procedures Manual in April 2010 in response to NIDDK's March 10 letter or, at least, when it later submitted its independent audit report for calendar year 2009. FFA Sciences argues that the audit report was accepted as meeting federal standards, found that FFA Sciences had sufficient internal controls, and did not question any expenditures.

Even if this documentation had been sufficient to address NIDDK's concerns, that would not excuse FFA Sciences' noncompliance with the requirements that it permit NIDDK to perform an on-site visit and give NIDDK access to pertinent records. In any event, FFA Sciences could not reasonably have thought that what it submitted in April 2010 was responsive to the concerns NIDDK had expressed regarding the rate of expenditures in relation to the progress reported on grant aims. As noted above, the account statement FFA Sciences submitted was a one-page document giving total accumulated expenditures by general category for the entire period November 13, 2008 through December 31, 2009. NIDDK had, however, requested statements that "detail the expenditures for the above listed totals," clearly referring back to the totals given on the PSC-272 reports for March 31, June 30, and December 31, 2009. NIH Ex. 6, at 6-7. The account statement contained no detail of the expenditures and no way to relate even general cost categories to the PSC-272 reports. In other words, it was obviously insufficient to address the questions raised.<sup>6</sup>

FFA Sciences suggests that it did not learn that the "accelerated rate" of the drawdowns was a concern until NIDDK's September 21, 2010 letter. FFA Br. at 14-15. This claim is not credible. NIDDK did not use the term "accelerated rate" until the September 21 letter, but the March 31, 2010 letter clearly sought an explanation for the amounts drawn

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<sup>6</sup> FFA Sciences suggests that NIDDK was not "truly dissatisfied" with the level of detail of this account statement, since NIDDK's letter of May 10, 2010 did not mention the lack of detail and since that letter requested a site visit to "seek further clarification of the scientific progress and to review the administrative and financial policies used to manage the grant." FFA Br. at 13; AF Ex. 1, Att. K. Nothing in the May 10 letter indicated that NIDDK was satisfied with FFA Sciences' response, however. Moreover, while NIDDK did not at that point ask for cost documentation, it did ask FFA Sciences to respond to the "Organizational System Review Questionnaire" by May 26 and set a tentative date (June 3) for a site visit by both program and grants management staff.

down, including the drawdown of \$450,000 (most of the initial award amount) by March 31, 2009. In addition, an NIDDK email in May 2010 explaining the reasons for the requested site visit referred to NIDDK's concern about the "significant" drawdowns and FFA Sciences' response repeated the statement of concern. NIH Ex. 8, at 36, 48.<sup>7</sup> Moreover, despite the fact that the September 21 letter did explicitly refer to the "accelerated rate" of drawdowns, FFA Sciences did not timely submit any document justifying the rate in response to that letter, even when given two extended deadlines by NIDDK and a further opportunity by the NIH Appeals Board to submit documents to address this concern. Indeed, as discussed below, the documentation ultimately submitted does not justify the drawdowns either.

The Policies and Procedures Manual partially responded to NIDDK's March 2010 letter, but did not respond to the request for account statements detailing the expenditures FFA Sciences had reported as a basis for the drawdowns. Even assuming the manual was in effect when the cash was drawn down (which is unclear since it is undated), FFA Sciences' failure to immediately account for the drawdowns gave NIDDK a legitimate basis to question whether the cash and other controls in the manual were actually applied and effective during the budget period at issue.

FFA Sciences' attempt to fault NIDDK for not accepting the audit report by Withers & Mann, LLP, as sufficient to address its concerns also has no merit. The report was not even issued by the auditors until October 5, 2010 (and it does not state when the audit work was done). AF Ex. 1, Att. F. The report therefore says nothing about the state of FFA Sciences' records before that date or what NIDDK would have found if it had been able to do a site visit in June or July, 2010, as requested. Moreover, the report covers only calendar year 2009 and simply does not address the issue of the accelerated rate of drawdowns in relation to scientific progress. While an "initial review" of the report by the Office of the Inspector General (IG) found it to be adequate to meet the audit requirements for for-profit organizations (which would include testing some grant transactions), it also noted that the report was submitted late. *Id.* More importantly, the report specifically states that the auditors "do not express an opinion on the effectiveness of the Company's internal control over financial reporting" and that providing an opinion on compliance with grant requirements "was not an objective" of the audit. *Id.* at pages 6-7 of the report. Thus, even if the audit report covered all of the relevant time period, the report's stated qualifications to the auditors' opinions render the report immaterial to the issues before us.

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<sup>7</sup> FFA Sciences also suggests that the September 21, 2010 letter did not take into account that pre-award costs were incurred beginning on November 13, 2008, as FFA Sciences' April 12, 2010 submission had indicated. The April 12, 2010 letter did not, however, specifically assert that FFA Sciences had sufficient pre-award expenses to justify the drawdowns, instead focusing mainly on the scientific issues. NIH Ex. 7. The attached account statement is for the period beginning November 13, 2008 but gives no breakdown of what pre-award costs FFA Sciences allegedly incurred. We also note that, as FFA Sciences' later submissions recognize, the 90-day pre-award period actually began November 16, not November 13.

In any event, FFA Sciences had effectively refused to agree to a site visit months before the audit report was issued and had failed to provide the information requested on the questionnaire enclosed with the original site visit request. NIDDK thus reasonably requested more specific and detailed information in September 2010, including supporting documentation such as time and effort reporting, to address not only the questions previously raised regarding the timing of cash drawdowns and any scientific progress, but also the questions raised by FFA Sciences' effectively denying NIDDK its right of access to the grantee's records.

Thus, we conclude that FFA Sciences failed to comply with the terms and conditions of its NIDDK award by failing to be responsive to NIDDK's requests for information and by refusing to permit NIDDK an on-site visit and access to its records, as required.

***FFA Sciences' failure to comply was material.***

We further conclude that the failure to comply was material, for several reasons. First, FFA Sciences' failure to comply with the requests for detailed statements to support the cash transaction reports and then for a site visit frustrated NIDDK's ability to investigate in a timely manner whether FFA Sciences' drawdowns complied with award terms and conditions governing cash transactions and how those drawdowns related to reported progress on grant aims.

Second, FFA Sciences failed to comply with more than one term and condition of the award, failing not only to provide information on request but also effectively refusing to permit an on-site visit and provide access to its records, as required.

FFA Sciences' failures on which NIDDK based its determination had also persisted over a lengthy period of time, starting at least by April 2010 and continuing through the end of that year, despite numerous opportunities given by NIDDK allowing FFA Sciences to correct the noncompliance by confirming a date for a site visit and/or providing the requested documentation. Before NIDDK took its enforcement action, moreover, it informed FFA Sciences several times that failure to timely comply would be considered a material failure justifying an enforcement action.

***Withholding of future funding for the project is authorized based on FFA Sciences' material failure to comply with the terms and conditions of its award for the initial budget period of the project.***

The regulation at 45 C.F.R. § 74.62(a) specifically authorizes an HHS awarding agency to "[w]ithhold further awards for the project or program" if the recipient of an award materially fails to comply with the terms and conditions of the award. Since we conclude

that FFA Sciences materially failed to comply with the terms and conditions of its award for the initial budget period of its project, we uphold the denial of any further award for the project.

FFA Sciences suggests that somehow NIDDK acted improperly in delaying and ultimately denying funding for the continuation application because NIDDK changed its reasons for not granting the continuation award. Specifically, FFA Sciences says that NIDDK first said that the continuation funding was delayed because of unavailability of funds, then said there were questions about scientific progress, and only later said the funds were denied for concerns about financial management. FFA Br. at 32-34.

We see nothing improper in NIDDK's actions. A non-competing continuation award is always subject to availability of funds, to satisfactory progress, and to the best interests of the federal government. FFA Sciences had notice of this through, among other things, the NIHGPS and the NGA. FFA Sciences' progress report submitted with its continuation application reported no progress on Aim 3. Also NIDDK reasonably questioned whether the project could continue as a study ancillary to the NASH CRN clinical trial (per the program announcement) after learning that NASH CRN had denied further serum samples. Yet, NIDDK delayed actually denying the continuation award on that basis while FFA Sciences appealed the denial of further samples from NASH CRN. Then, although Dr. Doo had erroneously said NIDDK would take administrative action to "terminate" the grant after the final rejection by NASH CRN of any further samples, NIDDK again simply delayed a decision while NIDDK sought further information from FFA Sciences about its expenditures in relation to its progress on the award.<sup>8</sup>

In any event, the NIH Appeals Board decision that is before us on appeal upheld the withholding of further funding for FFA Sciences' NAFLD project based on its finding that FFA Sciences had materially failed to comply with the terms and conditions of the initial award. That NIDDK may have had other reasons for delaying a formal determination on whether to make a continuation award is irrelevant. Since the finding on which the NIH Appeals Board decided to withhold further funding is supported by the record before us and the applicable law, we uphold that decision.

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<sup>8</sup> Dr. Doo obviously misspoke. There was no award to terminate at that point in time since no continuation award had been made. *See, e.g.*, 45 C.F.R. § 74.2 (definition of "termination"); § 74.62 (distinguishing termination from withholding of future awards). Moreover, FFA Sciences has not submitted any evidence that the reason it did not respond to NIDDK's requests was that it thought the grant had been terminated. Even assuming that Dr. Doo's statement caused some confusion, that would not explain FFA Sciences' failure to respond even after the December 20, 2010 letter acknowledged the misstatement and reiterated that failure to respond could lead to an enforcement action.

***Disallowance of the full amount of the award is authorized under the circumstances of this case.***

*The disallowance is reasonably related to the activity or action not in compliance.*

FFA Sciences points out that section 74.62(a) authorized NIH to disallow **only** costs “of an activity or action not in compliance.” According to FFA Sciences, this provision did not authorize NIH to disallow all of the funds awarded to it. The NIHGPS indicates that any enforcement action will depend on the “severity and duration” of the noncompliance and that, usually, NIH will give a grantee an opportunity to correct any noncompliance. NIH says it reasonably disallowed the full amount because it “simply did not have the information it needed to assess whether the grant expenditures were reasonable, allowable, and allocable.” NIH Br. at 15.

We conclude that, under the circumstances here, disallowance of the full amount awarded is consistent with section 74.62 and with the “severity and duration” of the noncompliance. FFA Sciences’ actions in repeatedly refusing to set a date for a site visit and to respond adequately to requests for information and supporting documentation kept NIH from fulfilling its responsibility to monitor the use of federal funds. Effectively, FFA Sciences denied timely access to any of FFA Sciences’ programmatic records as well as any records that would show whether and when FFA Sciences incurred the costs based on which it drew down federal funds under the award. Given FFA Sciences’ intransigence, which lasted over a long period of time despite repeated opportunities to correct the noncompliance and warnings about the potential consequences, there is no assurance that any of the funds were properly spent in compliance with the terms and conditions of the award.

FFA Sciences further argues that NIH’s action in disallowing **all** of the funds awarded and denying future funding constitutes an “unreasonable, disproportionate enforcement action” in the face of overwhelming evidence that it is “improper and unjust.” FFA Br. at 2. FFA Sciences says the action is especially unfair since Dr. Doo had estimated that, in order to achieve the progress reported by FFA Sciences, FFA Sciences would have had to expend \$150,000. *Id.* at 26. According to FFA Sciences, it “did perform – and NIH does not contest such performance – the proposed programmatic effort using best efforts” and submitted the required research reports, thus meeting the grant purpose. FFA Br. at 1. Dr. Doo’s estimate, however, was based on the progress **reported** by FFA Sciences. FFA Sciences cannot reasonably rely on that estimate or its reported progress after having frustrated efforts by Dr. Doo and NIDDK to verify the scientific claims in the progress report and to timely access documents to determine whether any progress claimed (and which NIH could verify) was made within the award period or the permitted 90-day pre-award period (as opposed to before the period covered by the award).

FFA Sciences also argues that NIH has confirmed it is not alleging fraud and that FFA Sciences has a financial management system with adequate controls, so NIH's "only real concern is access to cost documentation," but that NIH has had access to some of the documentation and materials since well before the enforcement action. FFA Br. at 3 (emphasis in original). As the contemporaneous record shows, however, NIH's concerns were not only with access to cost documentation, but with the accelerated rate of cash drawdowns in relation to the progress reported. As discussed above, what FFA Sciences submitted to NIH in a timely manner was clearly inadequate to address either concern. NIH did indicate that its concern about the adequacy of FFA Sciences' general accounting procedures had been resolved. Bd. 5/7/2012 ltr. We do not, however, read this as a concession by NIH that FFA Sciences had effectively applied its procedures and internal controls during the period in question.

FFA Sciences also argues that the disallowance is unfair and disproportionate because FFA Sciences has **now** submitted documentation showing that it incurred allowable expenditures in excess of the award amount.<sup>9</sup> Since the grant has not been closed out, FFA Sciences says, it is "reasonable and equitable for NIH to consider all of the cost materials in addressing any unsettled costs, or costs the NIH wants to examine." FFA Br. at 3. We reject this argument for the following reasons.

First, submitting the documentation to this Board on appeal did not cure the grantee's material failure to comply with the terms and conditions of the award that formed the basis for the NIH determination appealed. Submission of the documentation now cannot reasonably be considered timely compliance, especially in light of the history of intransigence and lack of cooperation discussed above.

Second, either doing a detailed review of the documentation ourselves or requiring NIH to do so at this point would undercut the grantor agency's authority to require a grantee either to timely identify a date for a site visit or to produce requested information and documentation (or both) when legitimate questions arise. NIH argues that FFA Sciences has not provided a reasonable explanation for why it did not submit the documents

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<sup>9</sup> FFA Sciences points to the November 22, 2011 teleconference held by the Board, arguing that NIH had agreed in the conference to review the documents identified in the September 21, 2010 letter if FFA Sciences submitted them and that it is arbitrary of NIH now to refuse to review those documents. This argument ignores the fact that NIH's initial commitment was to review the documents if submitted **by December 6, 2011**. During the conference, NIH indicated it might agree to a later date if FFA Sciences agreed to submit those documents and identified a schedule for doing so (which FFA Sciences did not do during the conference). The Board discussed with the parties steps to be followed **if** FFA Sciences informed the Board that it intended to submit the requested documents on a schedule acceptable to NIH. Instead of FFA Sciences formally agreeing as part of the Board's proceedings to submit the requested documents on a particular schedule, however, it opted to engage in settlement negotiations with NIH and the Board's proceedings were stayed. Nothing that occurred during the settlement negotiations could transform NIH's offer to review the documents **as part of the Board's proceedings** into an unconditional offer that would apply even if FFA Sciences did not timely avail itself of the offer.

sooner, and we agree, for reasons stated below. “To permit FFA Sciences to disregard the Agency’s multiple requests for documentation of its grant expenses, only to allow it yet another attempt to cure such non-compliance before the Board,” NIH says, “erodes the Agency’s ability to effectively and efficiently administer the grants program and discharge its duty to provide responsible stewardship of the grant funds.” NIH Br. at 22.

Moreover, FFA Sciences’ repeated failure to cooperate in setting a date for a site visit giving NIDDK access to its records in the face of a legitimate concern about the accelerated drawdowns in relation to scientific progress (followed by further delays in providing information and supporting documentation) raises questions about whether the documents now submitted are reliable and were in fact the basis for drawing down federal funds under the award. Indeed, FFA Sciences does not contend that the documents it submitted now show that the drawdowns were justified. Instead, the exhibit that summarizes expenses for the period November 16, 2008 through March 31, 2009, shows only \$84,549 in direct costs under the NIDDK grant award. AF Ex. 10, at 1. Applying the approved indirect cost rate of 106% (and assuming for this purpose that the direct costs are allowable and allocable to the award), this means that FFA Sciences could properly draw down less than \$200,000 in federal cash by March 31, 2009, rather than the \$450,000 it reported on its relevant PSC-272 cash transaction report.<sup>10</sup>

Even a cursory review of the documentation ultimately submitted raises further questions about compliance with grant terms that would need to be addressed, undercutting FFA Sciences’ assertions that its belatedly submitted documentation on its face is sufficient to establish the allowability of its costs and close out the grant. For example, the April 2010 account statement lists consortium costs of \$21,304.50, whereas the later more detailed report does not list any consortium costs (even as an unsupported “incurred” cost). Compare NIH Ex. 7, at 2, with AF Ex. 11, Tab B. Also the April 2010 account statement (for November 13, 2008 through December 31, 2009) showed a total of \$370,703.43 in direct costs, whereas the detailed report submitted in January 2012 lists total direct costs of only \$297,381.24 as “incurred” for the period November 16, 2008 through November 30, 2009. The difference in time periods (34 days) for the two statements would not seem to explain the discrepancy of over \$73,000, since the expected rate of expenditures was less than \$50,000 per month. The time and effort reports submitted in April 2012 raise other questions, such as whether costs incurred for other work was shifted to the NIDDK grant and whether all key personnel were keeping track of their actual time, as required. See, e.g., AF Ex. 11, Tab C at 1 and Tab D3 (all time for lab assistant B.M. charged to the award, even though timesheets for period 12/5/08 through 2/26/09 show time charged to project code different from code elsewhere used to identify costs of NIDDK award); AF Ex. 11, Tab D7 (reports showing investigator spent exactly two hours/day on NIDDK/NAFLD project, no time for any other activity, exactly 6 hours/day spent on indirect activities, and exactly 80 hours/pay period, with no holiday or leave

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<sup>10</sup> FFA Sciences does not acknowledge this fact, however. Nor does it claim to have accounted for any interest earned on the funds drawn down in advance of disbursements for allowable expenditures.

time), *compare* AF Ex. 10 (Expense Detail report showing all costs for that investigator charged as an indirect cost) and AF Ex. 10 (Time & Effort summary showing total direct/indirect project hours for various periods different from total amounts shown on time and effort reports for those periods).

In sum, NIH's disallowance of the full award amount was authorized and was reasonable. Given the severity and duration of the noncompliance, NIH had no adequate assurance that any of FFA Sciences' costs were properly charged to the NIDDK award. Moreover, the belated submission of the requested information and documents neither cured the noncompliance nor provided such assurance. Given the circumstances here, we do not consider the documents to be a reliable basis on which we could reduce the disallowed amount.

*FFA Sciences' reliance on a consultant's declaration is misplaced.*

In support of its argument that NIH (or the Board) should examine all of the documentation FFA Sciences ultimately submitted, FFA Sciences relies on a declaration by a consultant submitted for the first time on appeal to us. Specifically, FFA Sciences relies on the declaration by Jeffrey S. Duval, a Vice President with The Kenrich Group, LLC, an independent consulting firm retained by FFA Sciences' counsel to perform an "independent, objective review" of the submission of expenditures by FFA Sciences to NIH. AF Ex. 2.

FFA Sciences' reliance on its consultant's declaration is misplaced. First, the declaration indicates that the consultant did not have full information about the history of NIDDK's requests. For example, he nowhere even mentions the critical issue of the PSC-272 reports and the accelerated rate of drawdowns under the award. He also states that the September 21, 2010 request for information "appears to be duplicative of the audit that was already conducted" since much of that information "such as expenditure reports for direct and indirect expenses and related support documentation, had been reviewed" by the audit and that the government allows audit agencies to rely on the work of others and HHS had a good reason to rely on the Withers & Mann audit given that the IG had reviewed it." AF Ex. 2, ¶ 8. As noted above, however, that audit report is not material to the issues before us because of its limited objectives and scope, and because it was not issued until October 5, 2010 (**after** NIDDK had sent its September 21 letter) and did not address NIDDK's concerns.

The consultant also attests that, in his experience, "support documentation is typically audited at the grantee's facilities." *Id.* at ¶ 9. He does not acknowledge (and maybe does not know) that NIDDK made six requests to FFA Sciences for a site visit and gave FFA Sciences ample opportunity to confirm a date for a site visit before taking other action.

The consultant says that, having reviewed the cost documentation submitted to NIH on January 10 and April 24, 2012 and the audit report using the four standards in FAR cost principles (reasonableness, allocability, consistency, and conformance), he has “not found a reasonable basis on which to disallow all costs incurred” in relation to the NIDDK grant and has found that “FFA Sciences has fulfilled its obligations under the grant to adequately document its costs incurred” and the documentation is “reasonably sufficient for the NIH to determine the allowability” of costs charged to the grant. AF Ex. 2, ¶¶ 14-17. This is far different from a statement identifying which, if any, of the costs he found to be allowable under the cost principles. Moreover, the consultant does not explain how he could have evaluated the issue of consistent treatment of costs. His declaration indicates that he examined only the audit report and documentation for the costs charged to the NIDDK grant. *Id.* ¶¶ 5-6. The consistency principle addresses whether treatment of costs under the award is consistent with treatment of costs under other activities of the recipient. NIHGPS at 80.

Given these and other flaws in the basis for the consultant’s opinion that NIH’s action was unreasonable, we accord no weight to his opinion.

*FFA Sciences had notice that disallowance was a potential enforcement action that NIDDK might take.*

FFA Sciences also asserts (in support of its argument that NIH’s stated legal basis for the disallowance is inadequate) that NIH’s correspondence it uses to support its enforcement action “does not include disallowance as a potential penalty.” FFA Br. at 28. According to FFA Sciences, the fact that the September 21, 2010 and December 20, 2010 letters stated that enforcement action “could include suspension or termination of the grant award” suggests that “suspension or termination are the most severe enforcement actions contemplated.” *Id.*

This argument has absolutely no merit. Both section 74.62 and the NIHGPS notify grantees that disallowance of the costs of the activity or action not in compliance is a potential enforcement action. NIH was not required to notify FFA Sciences in advance which specific enforcement action NIH might take. Moreover, the record also shows that the September 21 letter said that “[f]ailure to provide complete and timely information may cause NIH to take **one or more** enforcement actions in accordance with 45 CFR 74.62 which could include suspension or termination of the grant award,” mentioned the possibility of designation as a high risk grantee, and referred to the Enforcement Actions section of the NIHGPS, with a web link to the statement. NIH Ex. 10, at 3 (emphasis added). The December letter had similar wording. NIH Ex. 13, at 1. Nothing in these letters can reasonably be read as limiting the potential enforcement actions to suspension or termination.

*The other grant cases on which FFA Sciences relies are distinguishable.*

FFA Sciences also argues that Board precedent “confirms that disallowances carried out under 45 C.F.R. § 74.62(a)(2) involve cases where deficiencies were identified in an audit or where specific programmatic grant requirements were not met.” FFA Br. at 29. According to FFA Sciences, “virtually every case” it “has been able to identify where the agency sought to disallow costs incurred based on 45 C.F.R. § 74.62(a)(2) involved either deficiencies identified in an audit or significant areas of programmatic non-compliance, circumstances that are not present here.” *Id.* at 30. FFA Sciences says that it “could not find a single Board case in which the entire grant amount was disallowed despite a successful audit and a compliant accounting system – circumstances that are not in dispute here.” *Id.*

We first note that not all of the cases FFA Sciences cites were based on a material failure to comply with grant terms and conditions. An awarding agency may disallow and recover any funds that are misspent or applied to unallowable costs, regardless of whether any noncompliance with program requirements is material. 45 C.F.R. §§ 74.71-73; NIHGPS at 138. Audits that identify unallowable costs charged to an award do not necessarily find that any noncompliance was material. Typically, in these cases, the Board will review documents a grantee submits in response to the disallowance to determine whether the disallowance amount should be reduced. Here, however, there was a material failure to comply with grant terms and conditions.

The disallowance here is distinguishable, moreover, because of its unique circumstances. Here, FFA Sciences’ own cash transaction reports raised questions about whether it was complying with grant terms and conditions, particularly in light of further questions about scientific progress on grant aims. Yet, FFA Sciences repeatedly failed to set a date for a site visit, effectively denying NIDDK timely access to its programmatic, administrative, and financial records. Then, when NIDDK requested written information and documentation to support the drawdowns reported, FFA Sciences repeatedly missed the deadlines set. When offered another opportunity by the NIH Appeals Board to submit documentation to address NIDDK’s stated concerns, FFA Sciences again failed to submit documentation to justify its drawdowns and to clarify when the work discussed in the progress report was done. The documentation ultimately submitted is not only untimely, but does not, in fact, justify the drawdowns. Yet, FFA Sciences has not been forthcoming about this additional failure to comply with grant terms and conditions, choosing instead to obfuscate the issue of when it incurred the costs based on which it drew down federal funds. FFA Sciences has cited no prior case in which a grantee had a comparable failure to comply with award terms and conditions. In any event, whether or not there is Board precedent for disallowing all award costs based on a material failure to comply is irrelevant since the Board decides each case on the facts before it.

***FFA Sciences' failure to comply is not excused or mitigated by NIDDK's actions.***

FFA Sciences raises a number of arguments that, in our view, are intended to obfuscate the real issues about its noncompliance and what prompted its actions. These arguments are not only irrelevant, but are not supported by the record. Moreover, they are undercut by the fact that, even now, FFA Sciences has not proffered documentation that would justify the accelerated rate at which it drew down federal funds.

FFA Sciences' main argument throughout both appeal processes has been that NIDDK's actions in seeking information and documentation from it were "retaliatory." FFA Br. at 35-39. FFA Sciences' allegations about NIDDK officials retaliating against it rely on assertions that are not supported by the contemporaneous written record.<sup>11</sup> We do not discuss these assertions in detail because we conclude that they are, in any event, irrelevant to our review of the NIH Appeals Board decision. First, FFA Sciences points to nothing in the grant terms and conditions that would excuse a grantee from responding to legitimate questions about its use of federal funds merely based on a question about the motivations of federal officials. Second, FFA Sciences had notice at least as of September 9, 2010 that higher officials had reviewed the matter and considered the NIDDK officials' actions to be justified. NIH Ex. 9, at 4. Yet, FFA Sciences still did not set a date for a site visit or timely respond to NIDDK's later requests for information and documentation.

FFA Sciences also tries to shift the blame to NIH in other ways. For example, FFA Sciences asserts that "there have been miscommunications and misunderstandings that regrettably impacted later access." FFA Br. at 3. FFA Sciences also says that NIH's position that FFA Sciences' submission is too late "ignores the significance of its numerous, although apparently errant, indications to the Grantee that the grant was terminated . . . ." Reply Br. at 2.

FFA Sciences has not presented any **evidence** that any miscommunications or misunderstandings in fact impacted its decision not to give NIDDK the access it sought. FFA Sciences did submit a declaration by Dr. Kleinfeld about how he perceived some of NIDDK's actions. Nowhere in that declaration, however, does he specifically aver that the **reason** FFA Sciences did not provide the information and access NIDDK sought was because he thought the grant had been terminated (one of the alleged miscommunications) or because he thought NIDDK's actions were retaliatory. AF Ex. 8,

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<sup>11</sup> For example, FFA Sciences asserts that its criticism of NIDDK officials was first made in its March 14, 2010 letter, before NIDDK's March 31 letter questioning the drawdowns. The March 14 letter, however, focuses on a critique of FFA Sciences' 2008 abstract in an email from a NASH CRN committee member who was not an NIDDK employee. NIH Ex. 6. The first letter accusing NIDDK officials of improper conduct was the August 2010 letter, sent after FFA Sciences' inadequate response to the March 31 letter and after it had refused NIDDK's requests for a date for a site visit.

at unnumbered pages 5-8.<sup>12</sup> Indeed, even if FFA Sciences had submitted a declaration averring such a reason, the credibility of such evidence would be questionable. The noncompliance continued even after NIDDK had clarified that it had made no decision about a continuation award and repeatedly warned FFA Sciences about the potential consequences of noncompliance. Given these factors and the fact that even the documentation FFA Sciences submitted late does not justify the accelerated rate of drawdown of federal funds – a fact about which FFA Sciences has been less than forthcoming, we do not think FFA Sciences can credibly claim that its noncompliance was because of a miscommunication or misunderstanding or because it thought NIDDK officials’ actions were retaliatory.

We also note that suspension and termination in the grant context are terms of art that simply did not apply to FFA Sciences’ situation. The only funds awarded to FFA Sciences were the funds for the initial budget period, which ended by its own terms on November 30, 2009. FFA Sciences could not reasonably believe, moreover, that the expiration of the award period ended FFA Sciences’ obligation to comply with the award terms and conditions. *See, e.g.*, 45 C.F.R. §§ 74.2; 74.61-74.62; NIHGPS at 129.

Finally, we note that FFA Sciences now admits that it made **three** submissions to NIH after the November 2011 teleconference (including a March 8, 2012 submission) and does not dispute NIH’s assertion that FFA Sciences’ Exhibit 10 (which it identified as the January 10, 2012 submission) in fact includes documents not submitted to NIH until March 8, 2012, after the negotiations broke down. FFA Sciences’ 9/4/12 response to NIH Surreply; NIH Surreply. We see this as part of a pattern of FFA Sciences mischaracterizing its interactions with NIH by providing incomplete or inaccurate information about what occurred.

Certainly, it is understandable that FFA Sciences would be concerned about its reputation if it believed, as it asserts, that NIDDK officials were accusing it of misrepresenting data in the 2008 abstract (an assertion the contemporaneous record does not support). FFA Sciences’ actions were not, however, consistent with how a reasonable person seeking to protect and enhance its reputation would act. FFA Sciences could have furthered a goal of protecting its reputation by promptly providing adequate information to NIDDK to

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<sup>12</sup> This declaration contains inconsistencies with the contemporaneous documentation of the parties’ actions and omits relevant information. For example, the declaration asserts that, after June 9, Dr. Kleinfeld “received no additional correspondence from NIDDK regarding the site visit or otherwise for more than three months.” *Id.* ¶ 13. The declaration neglects to mention that the June 9 email from Dr. Doo had repeated his earlier requests that FFA Sciences name a date for the site visit. The declaration also says that the proposed site visit “did not, to my understanding, contemplate the extensive discussion of expenditures under the grant.” *Id.* ¶ 13. FFA Sciences had been told of NIDDK’s concern about the drawdowns, however, and was also told to be prepared during the site visit to discuss its answers to the questions on the enclosed questionnaire, many of which related to expenditures under the grant. NIH Ex. 8, at 6, 31.

address its stated concern about the drawdowns in relation to scientific progress and by setting a date for an on-site visit, regardless of whether NIDDK would look at the data for the 2008 abstract during the visit. Instead, FFA Sciences' actions raise even greater concerns about the trustworthiness of the information and documentation ultimately provided.

***No further procedures are necessary.***

FFA Sciences' request for relief includes a request for a hearing. FFA Sciences says a hearing "would be beneficial in assisting the HHS Departmental Appeals Board in understanding the issues presented here." FFA Br. at 40.

In cases like this one where an evidentiary hearing is not otherwise required by law or regulation, the Board will approve a request for a hearing "if it finds there are complex issues or material facts in dispute the resolution of which would be significantly aided by a hearing, or if the Board determines that its decisionmaking otherwise would be enhanced by oral presentations and arguments in an adversary, evidentiary hearing." 45 C.F.R. § 16.11. Here, FFA Sciences has identified no complex issues or material facts in dispute that would be significantly aided by a hearing, and we see no need for a hearing to enhance our decisionmaking. The material facts are either undisputed or best resolved by review of the extensive contemporaneous evidence in the record regarding what occurred between the parties. While FFA Sciences itself has relied on two declarations, NIH has not sought to cross-examine the declarants. We have evaluated their statements against the written record to determine what weight to give them, to the extent they are relevant to an issue we need to resolve.

Moreover, we see no need to have a hearing to resolve the parties' remaining disputes over what occurred during settlement discussions since what occurred during those discussions is not material to our decision.

Finally, we deny FFA Sciences' request for attorney's fees and expenses under the Equal Access to Justice Act (EAJA). FFA Br. at 40. Under the Board's regulations establishing appeal rights and procedures for disputes involving discretionary project grants, no hearing on the record is required, so these proceedings are not the type of adversarial adjudication to which the EAJA applies. 45 C.F.R. Parts 13 and 16. In any event, FFA Sciences has not prevailed in this appeal, as would be required for an EAJA award.

