



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL



OFFICE OF AUDIT SERVICES, REGION IX  
90 - 7<sup>TH</sup> STREET, SUITE 3-650  
SAN FRANCISCO, CA 94103

July 26, 2012

**TO:** Francis S. Collins, M.D., Ph.D.  
Director  
National Institutes of Health

**FROM:** /Lori A. Ahlstrand/  
Regional Inspector General for Audit Services

**SUBJECT:** Syntrix Biosystems, Inc.'s Costs Claimed Under the Recovery Act for National Institutes of Health Grant 3R44CA094612-05S2 Were Unallowable (A-09-11-01011)

The attached final report provides the results of our review of Syntrix Biosystems, Inc.'s costs claimed under the American Recovery and Reinvestment Act of 2009 for National Institutes of Health (NIH) grant 3R44CA094612-05S2. This review was requested by NIH.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Janet Tursich, Audit Manager at (206) 615-2063 or through email at [Janet.Tursich@oig.hhs.gov](mailto:Janet.Tursich@oig.hhs.gov). We look forward to receiving your final management decision within 6 months. Please refer to report number A-09-11-01011 in all correspondence.

Attachment

cc:

Meredith Stein  
Director, Division of Risk Management & Audit Liaison,  
Office of Management Assessment  
National Institutes of Health



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL



OFFICE OF AUDIT SERVICES, REGION IX  
90 - 7<sup>TH</sup> STREET, SUITE 3-650  
SAN FRANCISCO, CA 94103

July 26, 2012

Report Number: A-09-11-01011

John A. Zebala, M.D., Ph.D.  
CEO, President, Principal Investigator  
Syntrix Biosystems, Inc.  
215 Clay Street, NW  
Suite B-5  
Auburn, WA 98001

Dear Dr. Zebala:

Enclosed, for your information, is a copy of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Syntrix Biosystems, Inc.'s Costs Claimed Under the Recovery Act for National Institutes of Health Grant 3R44CA094612-05S2 Were Unallowable*. This report was issued to the National Institutes of Health.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please direct them to the HHS action official noted on the following page. Please refer to report number A-09-11-01011 in all correspondence.

Sincerely,

/Lori A. Ahlstrand/  
Regional Inspector General  
for Audit Services

Enclosure

**HHS Action Official:**

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Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**SYNTRIX BIOSYSTEMS, INC.'S  
COSTS CLAIMED UNDER THE  
RECOVERY ACT FOR NATIONAL  
INSTITUTES OF HEALTH GRANT  
3R44CA094612-05S2  
WERE UNALLOWABLE**



Daniel R. Levinson  
Inspector General

July 2012  
A-09-11-01011

# *Notices*

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at <http://oig.hhs.gov>

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## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

# *Office of Inspector General*

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The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## *Office of Audit Services*

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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## **EXECUTIVE SUMMARY**

### **BACKGROUND**

The American Recovery and Reinvestment Act of 2009 (Recovery Act), P.L. No. 111-5, enacted February 17, 2009, included measures to modernize the Nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, and protect those in greatest need. Office of Management and Budget memorandum M-09-15, dated April 3, 2009, states that Federal agencies must take steps, beyond standard practice, to initiate additional oversight mechanisms to mitigate the unique implementation risks of the Recovery Act.

The Recovery Act provided approximately \$10.4 billion to the National Institutes of Health (NIH), including \$8.2 billion intended to stimulate the economy through the support and advancement of scientific research. NIH used these funds to award grants and cooperative agreements to research entities, including nonprofit and for-profit organizations, universities, hospitals, governments and their agencies, and occasionally individuals. The NIH Grants Policy Statement (December 2003), which was effective for all grants with budget periods beginning December 1, 2003, through September 30, 2010, details the general policy that all grantees must follow. The Grants Policy Statement requires for-profit organizations to maintain a time-and-effort reporting system that reflects daily after-the-fact reporting of hours expended on individual projects.

Under the Recovery Act, NIH awarded Syntrix Biosystems, Inc. (Syntrix), a commercial organization located in Auburn, Washington, a supplemental grant of \$200,000 for its Snap-To-It Probes Project (the project). The award was for the period September 30, 2009, through September 29, 2010.

### **OBJECTIVE**

Our objective was to determine whether the costs that Syntrix claimed against the Recovery Act grant were allowable under the terms of the grant and in accordance with applicable Federal requirements.

### **SUMMARY OF FINDINGS**

Of the \$200,000 of costs that Syntrix claimed against the Recovery Act grant, the entire amount was unallowable:

- For the \$126,783 of total direct costs claimed, we questioned as unallowable the entire amount because Syntrix's timesheets did not reflect employees' actual hours worked on the project.
- For the \$73,217 of total indirect costs claimed, we questioned as unallowable the entire amount based on our disallowance of total direct costs.

Syntrix did not adhere to its policies for recording and distributing employees' time and attendance to ensure that the costs claimed were allowable under the terms of the grant and in accordance with applicable Federal requirements.

## **RECOMMENDATIONS**

We recommend that NIH recover the \$200,000 that Syntrix claimed for unallowable costs. In addition, to ensure that Syntrix adheres to its policies for recording and distributing employees' time and attendance to properly account for costs claimed under Federal grants, we recommend that NIH establish additional monitoring and reporting requirements regarding Syntrix employees' time and attendance.

## **SYNTRIX BIOSYSTEMS, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, Syntrix took a strong position of nonconcurrency with our findings and recommendations. Syntrix disagreed with our application of Federal requirements and our assessment of its time-and-effort reporting system. Syntrix stated that recording the distribution of time that employees worked on the project as a percentage of the total recorded hours was a fully acceptable means of meeting NIH standards. As further evidence that it followed NIH standards, Syntrix attached to its comments signed certifications of employees' hours spent on the grant, dated December 2011. We have included Syntrix's comments as Appendix A. However, we have omitted the signed certifications because they contained personally identifiable information.

The Grants Policy Statement makes clear that the distribution of time worked must reflect employees' actual hours worked on specific projects rather than estimated percentages, and the information must be certified at least every pay period. Because the signed certifications that Syntrix provided us were dated more than a year after the end of our audit period, they do not constitute valid evidence that timesheets were verified and certified. After reviewing Syntrix's comments, we maintain that our findings and recommendations are valid.

## **NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, NIH concurred with our findings and our first recommendation. Regarding our second recommendation, NIH suggested a revision to the wording. NIH offered technical comments on the description of our methodology for calculating fringe benefits and indirect costs and our finding on unallowable total direct costs. We revised our report based on NIH's suggestions and have included NIH's comments in their entirety as Appendix B.

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## **INTRODUCTION**

### **BACKGROUND**

#### **American Recovery and Reinvestment Act**

The American Recovery and Reinvestment Act of 2009 (Recovery Act), P.L. No. 111-5, enacted February 17, 2009, included measures to modernize the Nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, and protect those in greatest need. Office of Management and Budget memorandum M-09-15, dated April 3, 2009, states that Federal agencies must take steps, beyond standard practice, to initiate additional oversight mechanisms to mitigate the unique implementation risks of the Recovery Act.

In accordance with the Recovery Act, the Office of Inspector General (OIG) provides oversight of covered funds within the U.S. Department of Health and Human Services to prevent fraud, waste, and abuse. In light of this oversight role, OIG conducts audits to determine whether Department grantees have claimed costs in accordance with applicable Federal regulations and cost principles.

#### **National Institutes of Health Funding Under the Recovery Act**

The Recovery Act provided approximately \$10.4 billion to the National Institutes of Health (NIH), including \$8.2 billion intended to stimulate the economy through the support and advancement of scientific research. NIH used these funds to award grants and cooperative agreements to research entities, including nonprofit and for-profit organizations, universities, hospitals, governments and their agencies, and occasionally individuals.

#### **Federal Requirements for Grantees**

NIH grantees are required to follow the cost considerations and principles in Federal regulations and the NIH Grants Policy Statement. Pursuant to 45 CFR § 74.27, the allowability of costs incurred by commercial organizations is determined in accordance with the provisions of the Federal Acquisition Regulation (FAR) at 48 CFR part 31. The NIH Grants Policy Statement (December 2003), which was effective for all grants with budget periods beginning December 1, 2003, through September 30, 2010, details the general policy that all grantees must follow.

#### **Syntrix Biosystems, Inc.**

Syntrix Biosystems, Inc. (Syntrix), is a private, Washington State-based biotechnology company dedicated to developing and commercializing therapeutic compounds and research platforms for the pharmaceutical, biotechnology, and research markets. Syntrix develops and commercializes research platforms and technologies for the study of DNA, RNA, proteins, and whole tissues. From Federal fiscal years 2001 through 2011, Syntrix received over \$15 million from NIH.

Under the Recovery Act, NIH awarded Syntrix \$200,000 for the period September 30, 2009, through September 29, 2010, consisting of \$126,783 for direct costs and \$73,217 for indirect costs. The direct costs consisted of salaries and wages of \$106,086 and fringe benefits of \$20,697. The indirect costs were based on a percentage of total direct costs; Syntrix negotiated with NIH the indirect cost rate. This grant was a supplement to a previous grant for Syntrix's Snap-To-It Probes project (the project).

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether the costs that Syntrix claimed against the Recovery Act grant were allowable under the terms of the grant and in accordance with applicable Federal requirements.

### **Scope**

We reviewed the total \$200,000 in costs that Syntrix claimed for the period September 30, 2009, through September 29, 2010, for NIH grant 3R44CA094612-05S2. All of the costs claimed were direct and indirect costs in support of the project.

We limited our assessment of Syntrix's internal controls to those that related to the objective of our audit. We performed fieldwork at Syntrix's office in Auburn, Washington, from July to September 2011.

### **Methodology**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed the terms of the grant award;
- reviewed Syntrix's pay rates and transactions related to salaries and wages;
- verified Syntrix's calculation of fringe benefits and reviewed its supporting documentation for the calculation;
- verified that Syntrix applied the correct indirect cost rates and properly calculated indirect costs;
- interviewed Syntrix officials to obtain an understanding of Syntrix's internal controls and accounting system; and
- reviewed Syntrix's independent audit reports for the calendar years ended December 2007, 2008, and 2009.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

## **FINDINGS AND RECOMMENDATIONS**

Of the \$200,000 of costs that Syntrix claimed against the Recovery Act grant, the entire amount was unallowable. Syntrix did not adhere to its policies for recording and distributing employees' time and attendance to ensure that the costs claimed were allowable under the terms of the grant and in accordance with applicable Federal requirements.

### **FEDERAL REQUIREMENTS**

Pursuant to 45 CFR § 74.27, the allowability of costs incurred by commercial organizations is determined in accordance with the provisions of the FAR at 48 CFR part 31. The FAR, section 31.201-2(a), states that a cost is allowable if it is reasonable and allocable. Section 31.201-3(a) states that a cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person in the conduct of competitive business. Section 31.201-4 states that a cost is allocable if it is assignable or chargeable to one or more cost objectives on the basis of relative benefits received or other equitable relationship.

The NIH Grants Policy Statement, Part II, subpart A, "Selected Items of Cost for Payroll Distribution," requires for-profit organizations to maintain a time-and-effort reporting system that reflects daily after-the-fact reporting of hours expended on individual projects unless the grants management officer approves an alternate system. Employees are personally responsible for recording all hours worked and all hours absent, recording the correct distribution of hours by project, and signing the timesheet or certifying the labor distribution in an automated system at the end of each pay period (NIH, Office of Acquisition Management and Policy, "Time and Effort Reporting for Commercial Organizations" (OAMP policy)). The OAMP policy requires that a supervisor cosign the timesheet or electronically certify individual time-and-effort reporting at the end of each pay period.

### **UNALLOWABLE TOTAL DIRECT COSTS**

Of the \$126,783 that Syntrix claimed for total direct costs, the entire amount was unallowable. Syntrix's timesheets did not reflect employees' actual hours worked on the project funded by the grant. Syntrix's total direct costs consisted of salaries, wages, and fringe benefits. Syntrix allocated these costs based on an estimated percentage of effort for each employee working on the grant instead of charging the actual number of hours worked on the grant. In addition, employee timesheets were not verified by the employees or certified by a supervisor. Although Syntrix's policies addressed the Grants Policy Statement's requirements, Syntrix did not follow those policies.

## **UNALLOWABLE TOTAL INDIRECT COSTS**

Of the \$73,217 that Syntrix claimed for total indirect costs, the entire amount was unallowable. These costs were based on a percentage of total direct costs, which we determined to be unallowable (see the previous section).

## **RECOMMENDATIONS**

We recommend that NIH recover the \$200,000 that Syntrix claimed for unallowable costs. In addition, to ensure that Syntrix adheres to its policies for recording and distributing employees' time and attendance to properly account for costs claimed under Federal grants, we recommend that NIH establish additional monitoring and reporting requirements regarding Syntrix employees' time and attendance.

## **SYNTRIX BIOSYSTEMS, INC., COMMENTS**

In written comments on our draft report, Syntrix took a "strong position of nonconcurrency" with our findings and recommendations. Syntrix disagreed with our application of Federal requirements and our assessment of its time-and-effort reporting system.

- Syntrix stated that recording the distribution of time that employees worked on the project as a percentage of the total recorded hours was a fully acceptable means of meeting NIH standards. Syntrix also stated that these standards do not specify that the distribution of employee time must be recorded in any particular units (e.g., hours).
- Syntrix stated that its time-and-effort reporting system conformed to NIH's standards. Specifically, Syntrix stated that its system included (1) after-the-fact recording of all hours on a daily basis, (2) recording the correct distribution of hours by project, and (3) signing or electronically certifying the labor distribution. In addition, Syntrix stated that an authorized company official electronically certified time-and-effort reporting at the end of each pay period. As further evidence that it followed NIH standards, Syntrix attached to its comments signed certifications of employees' hours spent on the grant, dated December 2011.
- Syntrix stated that our draft report did not refer to all aspects of Federal requirements governing allocability for commercial organizations, including FAR cost principles and the Grants Policy Statement. Specifically, Syntrix objected that our draft report had not addressed the NIH policy on allocating costs of closely related work.
- Syntrix objected to our statement in the draft report that timesheets could have been manipulated by anyone with access and requested that it be rescinded.

We have included Syntrix's comments as Appendix A. However, we have omitted the signed certifications that Syntrix provided because they contained personally identifiable information.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

The Grants Policy Statement makes clear that the distribution of time worked must reflect employees' actual hours worked on specific projects rather than estimated percentages, and the information must be certified at least every pay period. The OAMP policy specifies that "the employee is personally responsible for ... [r]ecording the correct distribution of hours by project or indirect category." Despite Syntrix's written statements to the contrary, Syntrix employees recorded only the number of hours worked each day, not which projects they worked on. The distribution of hours worked was based on supervisor estimates made every month or two. In addition, Syntrix employees did not verify timesheets, including their distribution of hours by project, and the supervisor did not certify them.

We reviewed all the timesheets during the audit period; there were no electronic signatures or markings to indicate any employee verified or any supervisor certified time and effort for each pay period. Because the signed certifications that Syntrix provided us were dated more than a year after the end of our audit period, they do not constitute valid evidence that timesheets were verified and certified.

Syntrix cites the Grants Policy Statement as support for its argument that grantees may allocate costs on any reasonable basis if the costs benefit two or more projects in proportions that cannot be determined, such as with costs for closely related work. We agree that grantees can allocate such costs to one project in such situations as long as the basis for the allocation is reasonable and the costs are otherwise allowable. In this case, however, Syntrix employees did not distribute their time between projects, and we were not able to evaluate the basis for the allocation.

After reviewing Syntrix's comments, we removed the statement that timesheets could have been manipulated by anyone with access, but we maintain that our findings and recommendations are valid.

## **NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, NIH concurred with our findings and our first recommendation. Regarding our second recommendation, NIH suggested a revision to the wording. NIH offered technical comments on the description of our methodology for calculating fringe benefits and indirect costs and our finding on unallowable total direct costs. We revised our report based on NIH's suggestions and have included NIH's comments in their entirety as Appendix B.

# **APPENDIXES**

## APPENDIX A: SYNTRIX BIOSYSTEMS, INC., COMMENTS



December 14, 2011

Lori A. Ahlstrand  
Office of Inspector General  
Office of Audit Services, Region IX  
90 – 7<sup>th</sup> Street  
Suite 3-650  
San Francisco, CA 94103

RE: Response to recommendations in OIG draft report A-09-11-01011 (enclosed) dated November 17, 2011 (due within 30 days or by Friday, December 15). Electronic PDF file without signature provided separately by email to Janet Tursich, Audit Manager, at [Janet.Tursich@oig.hhs.gov](mailto:Janet.Tursich@oig.hhs.gov) (206-615-2063).

Dear Ms. Ahlstrand,

We are in receipt your draft report dated November 17, 2011. We appreciate the due diligence and thoroughness of the field auditors in reviewing the processes followed at our Company. We were certainly surprised to read your recommendation after receiving praises from the field auditors on our compliance. We believe we are in compliance with all regulations and have provided the following detail in support of our compliance with applicable requirements and nonconcurrency with the draft report.

Under the Recovery Act, NIH/NCI awarded Syntrix Biosystems, Inc. (Syntrix) a supplemental salary-only grant of \$200,000 for its Snap-To-It research program originally funded as R44 CA 094612 (SNAP) for the 1 year period September 30, 2009, through September 29, 2010. The SNAP program has generated numerous accomplishments and resources for the scientific community, including:

1. Peer-reviewed publications (Morgan et. al., *Nucleic Acids Res.* 2008, 36, 3522-3530, and Ye et. al., *Biorg. Chem.* 2009, 37, 133-142)
2. Patents (U.S. Patent Appl. 11/834,533, Lyon, R. and Zebala, J.A. Conformationally constrained analytical probes. 53 pages. Published October 30, 2008).
3. Commercial products (2,2'-dipicolylamine CEPA, available from Glen Research Inc., see [www.glenres.com](http://www.glenres.com), search on 'syntrix')
4. Other manuscripts and patents in preparation related to data and discoveries generated over the previous 2 years.

As stated in the draft report, the Office of Audit Services (OAS) examines the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide (i) independent assessment of HHS programs and operations, and (ii) help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

As further elaborated, OMB memorandum M-09-15 dated April 3, 2009 states that Federal agencies must take steps, *beyond standard practice*, to initiate additional oversight mechanisms to mitigate the unique implementation risks of the Recovery Act. To this end, we acknowledge that *three* OAS auditors ( [REDACTED] ) were on site at Syntrix where they engaged Syntrix staff for *two full weeks* conducting a field audit of the above \$200,000 salary-only supplement.

The stated objective in the OAS draft report was to determine whether the Recovery Act costs that Syntrix claimed for reimbursement were *allowable, allocable, and reasonable* under the terms of the grant and in accordance with applicable Federal Requirements.

The applicable Federal Requirements are 48 CFR Subpart 31.2, Federal Acquisition Regulation (FAR) cost principles applicable to commercial organizations and NIH-specific policy and guidance, *including* the NIH Grants Policy Statement, dated December 1, 2003 (GPS)

The OAS draft report concluded 'Syntrix did not have adequate internal controls to ensure that the costs claimed for reimbursement were allowable, allocable, and reasonable under the terms of the grant and in accordance with applicable Federal requirements' using as its sole support the following three (3) alleged findings:<sup>1</sup>

1. "Syntrix's total direct costs consisted of salaries, wages, and fringe benefits. Syntrix allocated these costs based on an estimated percentage of effort for each employee working on the grant, not the actual number of hours worked."
2. "In addition, employee timesheets were not verified by the employees or certified by a supervisor,"
3. "and the timesheets could have been manipulated by anyone with access."

Syntrix takes its responsibility over the proper stewardship of Federal funds very seriously and has expended significant resources to ensure proper stewardship, full compliance with all Federal Requirements, and continued NIH confidence, including hiring additional accounting staff with NIH grant experience, the implementation of adequate controls and systems (e.g. no one person has complete control over all aspects of a financial transaction). In FY2010, Syntrix received an unqualified report from its annual government audit as a result of these measures.

Syntrix thus takes a *strong position of nonconurrence* with both the alleged findings and the recommendations in the OAS draft report. We elaborate the basis of our nonconurrence in the remainder of this document, demonstrating that the findings in the OAS draft report are based on an improper application of the Federal Requirements and a mischaracterization of the material facts. With this further clarification, Syntrix requests that OAS rescind its findings and amend its draft report accordingly.

<sup>1</sup> It is of note that OIG field auditors [REDACTED] indicated to the Syntrix Controller that Syntrix was in such exceptional compliance with the Federal Requirements that they intended to waive an exit interview. It appears the findings of the draft report are the result of an improper *post hoc ergo propter hoc* analysis.

**Office of Inspector General Note:** The deleted text has been redacted because it is personally identifiable information.

## A. The Federal Requirements

### A.1 Payroll Distribution for Supporting Time-and-Effort

The applicability of a particular set of cost principles depends on the type of organization. As noted in the GPS (p. 97), the FAR cost principles for commercial organizations are unique from the cost principles for all other types of organizations in that they are silent with respect to requirements for a *specific* payroll distribution system:

*“...Standards for payroll distribution systems are contained in the applicable cost principles (other than those for for-profit organizations)...”*

The GPS (p. 98) has elaborated the FAR cost principles to commercial organizations regarding an acceptable payroll distribution system further as NIH policy:

*“...NIH requires for-profit organizations to conform with industry standards to support salary and wage charges to NIH grants. Therefore, unless an alternate system is approved by the GMO, the grantee must maintain a time-and-effort reporting system for both professional and other-than-professional staff reflecting daily after-the-fact reporting of hours expended on individual projects or indirect activities. The system must record both hours worked and hours absent. This information must be certified by an AOO [Authorized Organizational Official] no less frequently than every pay period.”*

The NIH promulgates one type of acceptable payroll reporting system for commercial organizations at the following online site: [http://oamp.od.nih.gov/dfas/forproffitime\\_effort.asp](http://oamp.od.nih.gov/dfas/forproffitime_effort.asp).

The GMO (i.e. the NCI) for the supplemental salary-only grant awarded under the Recovery Act promulgates a substantially similar type of acceptable payroll reporting system for commercial organizations in its letter authored by [REDACTED] to commercial organizations (**Appendix 1**).

Syntrix’s payroll system employs a server-based electronic system based on an Excel timesheet in combination with manual data entry into QuickBooks that fully conforms to the (NIH and/or GMO) standards listed in the OAMP link above for an acceptable payroll system. Specifically:

- ✓ After the fact recording of hours (or fractions thereof) on a daily basis.<sup>2</sup>
- ✓ Recording all hours worked and all hours absent, whether or not they are paid.<sup>3</sup>
- ✓ Recording the *correct distribution* of hours by project or indirect category. The nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant or other factors (see section **A.3 Determining Allocability** below). To ensure accuracy, a listing of projects/indirect categories and their descriptions are provided.
- ✓ At end of each pay period, employee certifies the labor distribution in the system.

<sup>2</sup> OIG feedback to the Syntrix Controller indicates no disagreement that employees are performing this step.

<sup>3</sup> OIG feedback to the Syntrix Controller indicates no disagreement that employees are performing this step.

**Office of Inspector General Note:** The deleted text has been redacted because it is personally identifiable information.

- ✓ An authorized company official [AOO] (e.g., controller for supervisors, supervisors for junior staff for whom has supervisory oversight) electronically certifies individual time and effort reporting at the end of each pay period.

Note that ‘*correct distribution*’ by category as the phrase is used above in the written NIH/GMO standards in no way specifies or restricts that the distribution must be recorded in any particular units (e.g. hours) as suggested by the OAS draft report finding (#1 above) “Syntrix allocated these costs based on an estimated *percentage of effort* for each employee working on the grant, *not the actual number of hours* worked.” Thus, recording the correct distribution as a percentage of the total recorded hours is a fully acceptable means of meeting the standard (see also section **A.3 Determining Allocability** below). This finding in the OAS draft report is therefore improper, being without basis in written policy or law. We request the finding be rescinded.

Note that the Syntrix’s payroll system provides for, and contains, electronic verification by the employees and electronic certification by a supervisor in contradistinction to the OAS draft report finding (#2 above) “employee timesheets were not verified by the employees or certified by a supervisor.” Employee excel time sheets were electronically certified by employee and supervisor, and are thus compliant with the NIH/GMO standards. In particular, a cell in the excel spreadsheet was ‘clicked’ or ‘toggled’ to indicate certification by the relevant party. Electronic certification is commonplace and accepted in our modern society. For example, the electronic signature is accepted in both FDA and NIH submissions *in lieu* of a ‘wet’ signature. Moreover, electronic certification as described in the Syntrix payroll system is specifically permitted by the NIH/GMO standards. Finding #2 in the OAS draft report is therefore improper, being unsupported by law or policy, and contradicted by fact.<sup>4</sup> We request the finding be rescinded.

Note that ‘un-manipulatability’ is not an NIH/GMO standard for an acceptable payroll reporting system as suggested by OAS draft report finding (#3 above) “timesheets could have been manipulated by anyone with access.”<sup>5</sup> This finding in the OAS draft report is thus improper, being an improvisation without basis in policy or law. We request the finding be rescinded.

In addition to maintaining an acceptable Payroll System per NIH policies for commercial organizations, the FAR cost principles (48 CFR Subpart 31.201-2) applied to payroll also turn on, (i) reasonableness and (ii) allocability, wherein each is determined as follows:

<sup>4</sup> We provide ‘wet’ signatures for all 9 employees and their supervisors redundant to (i.e. in addition to) the previous electronic certifications in **Appendix 2** that give clear and incontrovertible evidence the OAS draft report finding #2 is unsupported by fact.

<sup>5</sup> Any payroll system can be defeated and manipulated by a determined individual(s), including a manual system with ‘wet’ signatures. Effort reporting is fundamentally an honor system, whether by accountants, attorneys or scientists. On the other hand, reasonable accounting controls should be in place that are *appropriate* for an organization. Although the Syntrix payroll system is fully compliant with NIH/GMO standards and has appropriate controls for an organization of ~10 employees working in a single converted warehouse laboratory/office where everyone’s whereabouts is known to everyone else at all times, it would not be appropriate for a large University having thousands of employees distributed across a wide geographic region. These facts notwithstanding, in the interest of being responsive to recommendations (i.e. not ‘findings’) by OIG for improved controls in our existing compliant electronic payroll system, we commit to add ‘wet’ signatures to the ‘per pay period’ certifications, and we have modified our *Time and Effort Reporting Policy* accordingly.

**A.2 Determining Reasonableness (48 CFR Subpart 31.201-3)**

*“...A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person in the conduct of competitive business.”*

**A.3 Determining Allocability (48 CFR Subpart 31.201-4 and the GPS)**

*“A cost is allocable if it is assignable or chargeable to one or more cost objectives on the basis of relative benefits received or other equitable relationship. Subject to the foregoing, a cost is allocable to a Government contract if it —*

*(a) Is incurred specifically for the contract;*

*(b) Benefits both the contract and other work, and can be distributed to them in reasonable proportion to the benefits received; or*

*(c) Is necessary to the overall operation of the business, although a direct relationship to any particular cost objective cannot be shown.”*

It appears the OAS draft report was made without complete reference to *all aspects* of the Federal Requirements governing allocability for commercial organizations; in particular, those embodied in the GPS (p. 84) that apply to Syntrix and that elaborate the FAR cost principles to commercial organizations as NIH policy regarding *allocability* of salary costs for *closely related work* as follows:

*“Allocation of Costs and Closely Related Work*

*When salaries or other activities are supported by two or more sources, issues arise as to how the direct costs should be allocated among the sources of support. In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit. A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles and the grantee’s financial management system includes adequate internal controls (for example, no one person has complete control over all aspects of a financial transaction). As a result, a grantee may allocate costs normally assignable to multiple projects to one of those projects.”*

Syntrix projects *all involve closely related work*. The GPS appropriately recognizes and provides provisions for, what all scientists already know; performing science is not the same as working at an automotive repair shop where work on automobiles is performed in serial fashion

and thus hours worked on each automobile can readily be determined and allocated.<sup>6</sup> The phrase *any reasonable basis* in the GPS is implemented at Syntrix through after-the-fact assessments by each employee scientist in full conformance with the principles of allowability, allocability and reasonableness as specified in the *Allocation of Costs and Closely Related Work* section of the GPS.<sup>7</sup> The *any reasonable basis* methodology employed by Syntrix for allocating payroll costs for closely related work *is in fact a right of Syntrix* under the Federal Requirements, *not* a violation of them.<sup>8</sup>

The OAS draft report finding #1 above is therefore an incorrect determination of the material facts associated with the *any reasonable basis* methodology of Syntrix and an improper (i.e. incomplete) application of the Federal Requirements. We request the finding be rescinded.

#### A.4 External Indicia

Employee effort on a project-by-project basis is further validated by external indicia that include hard-bound and doubly-signed dated laboratory notebooks for the SNAP research program maintained according to an *evidentiary standard* for determining invention priority in patent litigation disputes. Additionally, there are gigabytes of time stamped data on laboratory instruments for the SNAP project that corroborate both the bound laboratory notebooks and data in the conforming Syntrix payroll reporting system. The external indicia of factual evidence render the OAS position and recommendations simply untenable.

#### A.5 Conclusion

The Syntrix SNAP Recovery Act supplement precisely and successfully achieved the objectives of the Recovery Act at NIH, contributing to the employment of 9 scientists over the one year period of support, of which 4 were *newly hired* scientists specifically for, and because of, the SNAP Recovery Act supplement (**Table 1** in **Appendix 2**). Signed certifications by each of the above 9 scientists and their supervisors are provided herein as incontrovertible evidence fully refuting the OAS position and recommendations in its draft report (**Appendix 2**).

<sup>6</sup> For a typical senior chemist at Syntrix responsible for multiple projects who for example, begins their day at 8 am by starting 3 simultaneous synthetic reactions in the chemical fume hood, each for 3 different projects, each involving from 3 to 6 different and unique synthetic steps that require their own optimizations, each having their own timing over the course of days, who then turns to also reading a paper for one project, writing an annual report for another, managing 3 junior subordinate scientists each working on different projects, taking a telecon with a collaborating university scientist, and all the while simultaneously thinking about the various hypotheses and roadblocks on each of the projects, the notion that effort can be allocated across projects based on 'hours' worked as if the scientist were an automobile repair technician working in serial fashion on cars is nonsensical and would reflect a deep lack of understanding of how scientific research is actually conducted at the highest levels.

<sup>7</sup> OIG field auditors confirmed this in their interview with [REDACTED]. Furthermore, after-the-fact assessments by employees are necessarily constrained prospectively by Federal Requirements to fall within a narrow prespecified range dictated by the 'significant rebudgeting' threshold restriction (GPS, pg. 14), wherein a single direct cost budget category cannot deviate (increase or decrease) from the categorical commitment level for the budget period by more than 25 percent. Employees are informed of this threshold restriction by supervisors and/or management in order to ensure actual after-the-fact assessments prospectively conform with *both* the threshold restriction and the *any reasonable basis* standard promulgated by the GPS.

<sup>8</sup> OAS is encouraged to verify with [REDACTED]

**Office of Inspector General Note:** The deleted text has been redacted because it is personally identifiable information.

Syntrix is in *strong nonconcurrency* with both the alleged findings and the recommendations in the OAS draft report. Syntrix properly employed and complied with Federal Requirements governing: (i) standards that determine an acceptable payroll distribution system including after-the-fact input and electronic certification for each pay-period from each employee and their supervisor, (ii) cost principles of *reasonableness* and *allocability*, and (iii) the allocation of costs for activities involving *closely related work*. In all regards, Syntrix met and exceeded standards aimed at eliminating waste, abuse, and mismanagement.

The OAS draft report is based on an incomplete and improper application of the Federal Requirements and a mischaracterization of the material facts, in what is potentially an over exuberant application of the “*beyond standard practice*” guidance provided in OMB memorandum M-09-15 of the Recovery Act. The *beyond standard practice* guidance is not a directive to federal agencies to improperly ‘claw-back’ Recovery Act funds from small businesses, as such a strategy would be self-defeating to the very objectives of the Recovery Act itself, particularly with respect to nascent U.S. drug discovery and biotechnology companies like Syntrix that remain one of the few promising and bright, but fragile sectors of the U.S. economy.

We have detailed the factual basis of our nonconcurrency and provided the relevant citations to the Federal Requirements that together incontrovertibly support our nonconcurrency. We request that OAS immediately rescind its findings and amend its draft report accordingly.

Yours truly,

A handwritten signature in black ink, appearing to read "John A. Zebala". The signature is fluid and cursive, with a long horizontal stroke at the end.

John A. Zebala, MD, PhD  
President and CEO

Appendix 1 – Letter from [REDACTED]

**Employee Responsibilities**

Whether a manual or automated time and effort reporting system is in place, the employee is personally responsible for:

- After the fact recording of hours (or fractions thereof) on a daily basis.
- Recording all hours worked and all hours absent. All hours should be recorded whether or not they are paid.
- Recording of hours on the timesheet in ink (manual system only).
- Recording the correct distribution of hours by project or indirect category. The nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant or other factors. To ensure accuracy, a listing of project numbers/indirect categories and their descriptions should be provided in writing to each employee.
- Any changes/corrections to timesheets should be made by the employee and must show what was initially recorded, i.e., no erasures or "white out" of entries. The employee also must initial any change(s).
- At the end of each pay period, the employee must sign the timesheet or electronically certify the labor distribution in an automated system.

**Office of Inspector General Note:** The deleted text has been redacted because it is personally identifiable information.

## APPENDIX B: NATIONAL INSTITUTES OF HEALTH COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

JUN 12 2012

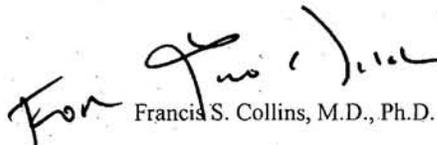
TO: Lori A. Ahlstrand  
Regional Inspector General for Audit Services, Region IX

FROM: Director, NIH

SUBJECT: General and Technical Comments on the Office of Inspector General's Draft Report, *Syntrix Biosystems, Inc.'s Costs Claimed Under the Recovery Act for National Institutes of Health Grant 3R44CA094612-05S2 Were Unallowable* (A-09-11-01011)

Attached are the National Institutes of Health's comments on the OIG's draft report, *Syntrix Biosystems, Inc.'s Costs Claimed Under the Recovery Act for National Institutes of Health Grant 3R44CA094612-05S2* (A-09-11-01011).

We appreciate the opportunity to review and comment on the draft report. Should you have questions or concerns regarding our comments, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

  
Francis S. Collins, M.D., Ph.D.

Attachments:  
NIH General Comments on OIG Draft Report A-09-11-01011  
NIH Technical Comments on OIG Draft Report A-09-11-01011

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT, ENTITLED SYNTRIX BIOSYSTEMS, INC.'S COSTS CLAIMED UNDER THE RECOVERY ACT FOR NATIONAL INSTITUTES OF HEALTH GRANT 3R44CA094612-05S2 WERE UNALLOWABLE (A-09-11-01011)**

The National Institutes of Health (NIH) appreciates the review conducted by the OIG and the opportunity to provide clarifications on this draft report. We respectfully submit the following general comments. Technical comments are included as a separate attachment.

***OIG Finding 1: The OIG recommends that NIH recover the \$200,000 that Syntrix claimed for unallowable costs (page 11).***

The NIH concurs with the OIG's finding and corresponding recommendation regarding Syntrix Biosystems, Inc.'s costs claimed under the Recovery Act for NIH grant number 3R44CA094612-05S2. We intend to recover the costs, as recommended.

***OIG Finding 2: The OIG recommends that NIH ensure that Syntrix adheres to its policies for recording and distributing employees' time and attendance to properly account for costs claimed under Federal grants (page 11).***

The NIH concurs with the OIG's finding and would like to clarify the corresponding recommendation regarding Syntrix Biosystems, Inc.'s costs claimed under the Recovery Act for NIH grant number 3R44CA094612-05S2.

We suggest that the recommendation be amended to read, "In order to ensure that Syntrix adhere to its policies for recording and distributing employees' time and attendance to properly account for costs claimed under Federal grants, the OIG recommends that NIH establish additional monitoring and reporting requirements regarding Syntrix employees' time and attendance."

**TECHNICAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT, ENTITLED *SYNTRIX BIOSYSTEMS, INC.'S COSTS CLAIMED UNDER THE RECOVERY ACT FOR NATIONAL INSTITUTES OF HEALTH GRANT 3R44CA094612-05S2 WERE UNALLOWABLE (A-09-11-01011)***

The National Institutes of Health (NIH) appreciates the review conducted by the OIG and the opportunity to provide comments on this Draft Report. We respectfully submit the following technical comments.

**I. Technical Comments –**

1. **Page 2**, under “Methodology,” the 4<sup>th</sup> bullet: We request that the OIG clarify what aspects of the fringe benefit and indirect cost rates were verified, i.e., the calculation of the rates and/or the application of the rates to the grant award.
2. **Page 3**, under “Unallowable Total Direct Costs,” fourth sentence: The NIH recommends the following revision: “Syntrix allocated these costs based on an estimated percentage of effort for each employee working on the grant, instead of charging the actual number of hours worked on the grant.
3. The NIH requests that the Action Official for this report be designated as:

Meredith Stein  
Director, Division of Risk Management & Audit Liaison  
Office of Management Assessment  
Office of Management  
National Institutes of Health (NIH)

We request that Ms. Stein be designated as the Action Official due to the nature of the findings. Full resolution of the recommendations may require working across the agency, which this Action Official has the authority and flexibility to carry out.