Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# BIO SIGNAL GROUP CORP., DID NOT ALWAYS CLAIM RECOVERY ACT COSTS IN ACCORDANCE WITH FEDERAL REQUIREMENTS

*Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.*


James P. Edert
Regional Inspector General

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**OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

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## EXECUTIVE SUMMARY

### BACKGROUND

The National Institute of Neurological Disorders and Stroke (NINDS) is 1 of 27 institutes and centers of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services. NINDS's mission is to reduce the burden of neurological disease. To support this mission, NINDS provides grants-in-aid to public and private institutions and individuals in fields related to its areas of interest, including research project, program project, and research center grants.

The American Recovery and Reinvestment Act of 2009 (Recovery Act), P.L. No. 111-5, provided $8.2 billion to NIH to stimulate the economy through the support and advancement of scientific research. Of the $8.2 billion, NINDS was given approximately $400 million to support projects which advance neuroscience research and positively impact the neurological health of the country.

Pursuant to 45 CFR § 74.27(a), the allowability of costs incurred by commercial organizations is determined in accordance with the provisions of the Federal Acquisition Regulation at 48 CFR part 31. In addition, 45 CFR § 74.21 contains financial management system requirements for awards and subawards to grantees. Policy requirements that serve as the terms and conditions of NIH grant awards are published in the *National Institutes of Health Grants Policy Statement* (Grants Policy Statement).

Bio Signal Group Corp. (Bio Signal), a for-profit company in Brooklyn, New York, develops and sells proprietary technologies for monitoring brain activity. On March 30, 2010, NINDS used Recovery Act funds to award Bio Signal a 3-year, Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies Pilot Program grant (NIH grant number 1RC3NS070658-01) totaling $2,949,240. The purpose of the grant was to develop and clinically test a miniaturized brain wave monitor for use by hospital emergency departments. During the period April 1, 2010, through July 27, 2011, Bio Signal claimed $996,699 for salary, fringe benefits, equipment, travel, consultants, other direct costs, and facilities and administrative (F&A) costs.

### OBJECTIVE

Our objective was to determine whether Bio Signal claimed costs in accordance with the terms of the grant and applicable Federal regulations.

### SUMMARY OF FINDINGS

Bio Signal did not always claim costs in accordance with the terms of the grant and applicable Federal regulations. Of the $725,318 in costs that we reviewed, Bio Signal claimed $581,174 in allowable costs. However, the remaining costs totaling $144,144 were not allowable. Specifically, Bio Signal claimed salary ($106,801) and related F&A costs ($14,396) that were unallowable because the costs did not reflect employee time and effort actually devoted to the

Recovery Act grant. In addition, Bio Signal improperly allocated payroll taxes ($13,020) to the Recovery Act grant. Bio Signal also claimed reimbursement of employee fringe benefit costs ($9,927) that were not reasonable for the performance of the award and were therefore unallowable.

## RECOMMENDATIONS

We recommend that NIH require Bio Signal to:

- refund $144,144 to the Federal Government,
- ensure that costs charged to the Recovery Act grant reflect employees' actual effort and related salary not estimates, and
- establish procedures for obtaining from employees documentation supporting health insurance premium costs.

## BIO SIGNAL GROUP CORP., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Bio Signal stated that the disallowance of salary costs was unreasonable and provided additional documentation to support these costs. Bio Signal also provided additional supporting documentation related to its fringe benefits costs. Bio Signal did not indicate concurrence or nonconcurrence with our findings related to F&A costs or payroll taxes. Finally, Bio Signal described improvements it had made to its financial administration policies and procedures since January 2011.

After reviewing Bio Signal's comments and additional documentation provided, we revised our findings and related recommendations accordingly. Specifically, we adjusted our findings related to certain salary costs and related payroll taxes and fringe benefits. Bio Signal's comments appear as Appendix A. We did not include the attachments to the comments because of their volume and inclusion of personally identifiable information.

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

In written comments on our draft report, NIH concurred with our recommendations. NIH also made two technical comments on our draft report, which we addressed as appropriate. NIH's comments are included in their entirety as Appendix B.

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# INTRODUCTION

## BACKGROUND

### National Institute of Neurological Disorders and Stroke

Within the U.S. Department of Health and Human Services, the National Institutes of Health (NIH) is the steward of medical and behavioral research for the nation. The National Institute of Neurological Disorders and Stroke (NINDS) is 1 of 27 NIH institutes and centers. NINDS's mission is to reduce the burden of neurological disease. To support this mission, NINDS provides grants-in-aid to public and private institutions and individuals in fields related to its areas of interest, including research project, program project, and research center grants.

### American Recovery and Reinvestment Act

The American Recovery and Reinvestment Act of 2009 (Recovery Act), P.L. No. 111-5, provided $8.2 billion to NIH to stimulate the economy through the support and advancement of scientific research. Of the $8.2 billion, NINDS was given approximately $400 million to support existing and pending peer-reviewed projects and trans-NIH programs that solicited innovative ideas and research projects. NINDS used its funds to support outstanding projects that were consistent with the goals of the Recovery Act, and which will advance neuroscience research and positively impact the neurological health of the country.

Recovery Act funds were used to award grants and cooperative agreements to research entities including nonprofit and for-profit organizations, universities, hospitals, research foundations, governments and their agencies, and occasionally individuals.

### Federal Requirements

Pursuant to 45 CFR § 74.27(a), 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. In addition, 45 CFR § 74.21 contains financial management system requirements for awards and subawards to grantees. Policy requirements that serve as the terms and conditions of NIH grant awards are published in the *National Institutes of Health Grants Policy Statement* (Grants Policy Statement).

### Bio Signal Group Corp.

Bio Signal Group Corp. (Bio Signal), a for-profit company in Brooklyn, New York, develops and sells proprietary technologies for monitoring brain activity. On March 30, 2010, NINDS used Recovery Act funds to award Bio Signal a 3-year, Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies Pilot Program grant (NIH grant number 1RC3NS070658-01) totaling $2,949,240. The purpose of the grant was to develop and clinically test a miniaturized brain wave monitor for use by hospital emergency departments.[1]

[1] The monitor, known as an electroencephalogram machine, measures electrical brain activity.

During the period April 1, 2010, through July 27, 2011, Bio Signal claimed $996,699 for salary, fringe benefits, equipment, travel, consultants, other direct costs, and facilities and administrative (F&A) costs.[2]

## OBJECTIVE, SCOPE, AND METHODOLOGY

### Objective

Our objective was to determine whether Bio Signal claimed costs in accordance with the terms of the grant and applicable Federal regulations.

### Scope

We limited our review to costs claimed by Bio Signal during the period April 1, 2010, through July 27, 2011. We reviewed $725,318 of the $996,699 (73 percent) claimed by Bio Signal during this period.

We limited our assessment of Bio Signal's internal controls to those that related to our objective. We conducted fieldwork at Bio Signal's administrative offices in Brooklyn, New York from July through August 2011.

### Methodology

To accomplish our objective, we:

- reviewed relevant Federal requirements;
- obtained Bio Signal's grant application package and notice of grant award;
- interviewed Bio Signal personnel to gain an understanding of Bio Signal's accounting systems and internal controls;
- reviewed Bio Signal's fiscal procedures and cost allocation methodology;
- analyzed selected costs for allowability; and
- discussed our results with Bio Signal officials.

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

[2] F&A costs are indirect costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or other institutional activity. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that are usually treated as F&A costs. According to the terms of the award, Bio Signal was limited to $232,046 in F&A costs over the 3-year award.

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 objectives.

## FINDINGS AND RECOMMENDATIONS

Bio Signal did not always claim costs in accordance with the terms of the grant and applicable Federal regulations. Of the $725,318 in costs that we reviewed, Bio Signal claimed $581,174 in allowable costs. However, the remaining costs totaling $144,144 were not allowable. Specifically, Bio Signal claimed salary ($106,801) and related F&A costs ($14,396) that were unallowable because the costs did not reflect employee time and effort actually devoted to the Recovery Act grant. In addition, Bio Signal improperly allocated payroll taxes ($13,020) to the Recovery Act grant. Bio Signal also claimed reimbursement of employee fringe benefit costs ($9,927) that were not reasonable for the performance of the award and were therefore unallowable.

### UNALLOWABLE COSTS

#### Salary Costs

Pursuant to section 31.201-2 of the FAR, to be allowable a cost must be reasonable for the performance of the award, allocable to the award, and must comply with the terms established by the awarding agency, among other requirements. Pursuant to the Grants Policy Statement in effect at the time of the grant award (NIH Grants Policy Statement, 12/03), to be allowable under a Federal award, salary costs must be based on a payroll distribution system that conforms with industry standards to support salary and wage charges, reflects daily after-the-fact reporting of hours expended on individual projects or indirect activities, and records both hours worked and absent. This information must also be certified by an Authorized Organizational Official no less frequently than every pay period.

Bio Signal claimed salary costs of $106,801 that were unallowable because the costs did not reflect employee time and effort actually devoted to the Recovery Act grant. Bio Signal implemented procedures requiring its 17 employees that charged time to the Recovery Act grant to record their time and effort on monthly timesheets. However, four of the employees did not complete a timesheet for 1 or more months during our audit period. For these employees, a Bio Signal official stated that he estimated the number of hours charged to the grant. In addition, the same Bio Signal official stated that he increased the number of hours charged to the grant on four other employees' monthly timesheets because he felt the timesheets did not accurately reflect the actual hours worked on the project.

Bio Signal also claimed F&A costs totaling $14,396 that were directly related to the unallowable salary costs and were therefore unallowable. Specifically, Bio Signal allocated F&A costs based on employee time and effort percentages. We recalculated the F&A costs to be charged to the Recovery Act grant using actual salaries paid less the unallowable salary charges identified above.

**Payroll Taxes**

Pursuant to section 31.201-4 of the FAR, "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."

Bio Signal claimed unallowable payroll tax costs totaling $13,020. To allocate payroll taxes to the Recovery Act grant, Bio Signal applied payroll tax rates to total salaries paid to its 17 employees.[3] However, Bio Signal used estimated–not actual–salary amounts. We recalculated the payroll taxes charged to the Recovery Act grant using actual salaries paid less the unallowable salary charges identified above.

**Fringe Benefits**

Pursuant to section 31.205-6(m) of the FAR, fringe benefits costs are allowable to the extent that they are reasonable and are required by law, employer-employee agreement, or established company policy. Pursuant to 45 CFR § 74.21(b)(7), a recipient's financial management system shall provide for accounting records, including cost accounting records, that are supported by source documentation.

Bio Signal claimed unallowable fringe benefit costs totaling $9,927. Bio Signal reimbursed employees for health insurance premium costs, but did not require employees to provide documentation to support these expenditures. This occurred because Bio Signal did not have procedures requiring employees to provide documentation supporting reimbursement of fringe benefit costs.

**RECOMMENDATIONS**

We recommend that NIH require Bio Signal to:

- refund $144,144 to the Federal Government,
- ensure that costs charged to the Recovery Act grant reflect employees' actual effort and related salary not estimates, and
- establish procedures for obtaining from employees documentation supporting health insurance premium costs.

[3] As of July 27, 2011, Bio Signal calculated and allocated payroll taxes for 14 of the 17 employees that charged time to the Recovery Act grant.

## BIO SIGNAL GROUP CORP., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Bio Signal stated that the disallowance of salary costs was unreasonable and provided additional documentation to support these costs. Bio Signal also provided additional supporting documentation related to fringe benefits costs. Bio Signal did not indicate concurrence or nonconcurrence with our findings related to F&A costs or payroll taxes. Finally, Bio Signal described improvements it had made to its financial administration policies and procedures since January 2011.

After reviewing Bio Signal's comments and additional documentation provided, we revised our findings and related recommendations accordingly. Specifically, we adjusted our findings related to certain salary costs and related payroll taxes and fringe benefits. Bio Signal's comments appear as Appendix A. We did not include the attachments to the comments because of their volume and inclusion of personally identifiable information.

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

In written comments on our revised draft report, NIH concurred with our recommendations. NIH also made two technical comments on our draft report, which we addressed as appropriate. NIH's comments are included in their entirety as Appendix B.

# APPENDIXES

# APPENDIX A: BIO SIGNAL GROUP CORP., COMMENTS

BIOSIGNAL
Life Science Solutions

Bio-Signal Group Corp.
Email | info@biosignalgroup.com
Web | www.biosignalgroup.com
Fax | +1 212.253.4243

Mr. James P. Edert
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

**RE: Audit Report Number A-02-11-02009, Bio-Signal Group Corp.**

May 3 2012

Dear Mr. Edert,

We would like to take this opportunity to provide our response to your Draft Report Number A-02-11-02009 based on a 2011 audit of our company, Bio-Signal Group Corp. ("BSG"). The auditors' findings were also communicated to BSG verbally in a Grant Exit Conference meeting on November 17, 2011, and also electronically by the audit team in various emails to our Chief Financial Officer. We respectfully request that HHS consider these comments to the draft audit report.

At the outset we would like to thank HHS for conducting the audit in a professional and efficient manner and for clearly communicating with BSG throughout the audit process. We appreciate the experience and believe it was beneficial to our company. BSG is fully committed to serving as an effective steward of federal funds, and we look forward to working with you to resolve the audit findings.

This letter is structured into five sections:

I. Brief background on BSG and the grant in question
II. The auditors' preliminary findings and our reasons for response
III. Discussion of your preliminary findings
IV. Corrective actions taken by BSG
V. Conclusion

If you have comments or questions about anything in this letter, we would be happy to respond, and we welcome the opportunity to discuss this with you in person in greater detail.

**Section I - Brief background on BSG and the grant in question**

BSG is a Brooklyn, NY start-up formed to transform neuroscience discoveries into tools to neuroscience research and clinical brain monitoring systems to improve patient care. In we believe that rapid functional brain monitoring in the form of electroencephalography ("EEG") underutilized, and that as many as 12.4M people every year visit US Emergency Departments ("ED's") and fail to get a rapid EEG, with serious or even fatal consequences for patients and increasing health care costs for hospitals. Despite the documented benefits of rapid EEG in the our market research found that only 2% of ED's have access to an EEG system, and only 1/3 of ED's can get an EEG recorded in under 4 hours. Our corporate mission is thus to bring EEG to

ED's, and to make rapid, easy brain monitoring generally available anywhere at any time. We therefore been developing our *micro*EEG system (www.microeeg.com), a wireless, inexpensive, miniature EEG system developed specifically with the challenging ED environment in mind. In future, we also see many potential applications for *micro*EEG in settings like physicians' offices, schools, rural areas, third world countries, etc. Exhibit 1 shows a recent press report that shows specifically how a researcher is using *micro*EEG in her clinical trial to improve pediatric malaria patient care in Africa.

The grant in question (1RC3NS070658-01, "Putting EEG in the Emergency Department") was awarded to support commercialization of *micro*EEG. The project period is 04/01/2010 – 03/31/2013. The application had three specific aims: 1) to finalize a clinical grade *micro*EEG system (engineering); 2) to generate clinical trial evidence as to the efficacy of *micro*EEG (clinical trials); and 3) to obtain FDA approval for *micro*EEG. We believe we have met all key milestones that underpin the three aims: we provided a clinical grade *micro*EEG system for a clinical trial that began in spring 2011 and continue to improve this system based on clinical feedback; we have just completed in February 2012 a 260 patient clinical trial at two prominent NYC-area hospitals (Kings County and SUNY University) ED's which provides compelling clinical evidence for the use of *micro*EEG in the ED; we have submitted our FDA 510(k) application in September 2011 to obtain approval to market *micro*EEG. Exhibit 2 shows our recently submitted progress report. We believe that this progress report demonstrates we have delivered what we promised to do on this grant and are meeting all planned milestones.

The grant represents critical support for BSG because we are a small company (10 employees) in an early stage of development. Until we obtain FDA approval for the device, we are unable to earn revenues from sale of product. BSG is entirely dependent on grant funding and private sources of capital. We were thrilled to have the opportunity to take on this project as it has been having a transformative impact on our company. Early stage companies like ours are typically at a disadvantage vs. larger companies in terms of funding product development, clinical trials and regulatory approval. We are excited that by the time the project period ends in early 2013, thanks to this support, we will be able to start actually selling *micro*EEG. This should have a positive impact on patient care and health care costs, and at the corporate level, generate new jobs in the economically distressed Empire Zone area of New York in which we are located.

**Section II - The auditor's preliminary findings and our reasons for response**

The draft audit report findings discussed in this letter concern salary disallowances and health insurance reimbursement disallowances. Based on the draft report we understand that $136,689 concern salary disallowances and $11,752 concern health insurance reimbursement disallowances.
To simplify, the auditors' salary disallowances fall into two general categories:

- Inadequate documentation: missing and/or incomplete timesheets for certain employees for certain months.
- Modified timesheets: discrepancies between the time documented and used for allocating salary to the grant and the time documented and recorded by certain employees.

We focus on these findings in this letter. We note that in all the cases we will discuss we went and conducted interviews in March 2012 with the employees in question regarding the disallowed time. We were explicit about informing each of them at the outset that they were under no

to respond in any particular way and they were not in trouble whatsoever and could speak freely about the disallowed time.

There are two principal reasons for our response at this stage.

We believe the recommended disallowances are in some cases unsustainable and in others unduly harsh. The auditors did not take into account several records of employee grant activity and disallowed the entirety of a salary charge even where these records confirm the employee's grant activity during the period in question. We have provided these records as exhibits to this response. Furthermore, the auditors appear to have overlooked the fact that in the context of complex scientific research an employee's supervisor often has the most reliable understanding of the employee's effort, and a particular understanding of how that effort benefits various projects. BSG management therefore reviewed timesheets in order to catch errors and omissions, and corrections to the labor records were made accordingly. As discussed in detail below, BSG can demonstrate that the employee salary charges in question are based on effort that was allocated to the grant in a manner that is consistent with (a) each employee's grant-related activity, (b) relevant documentation that supports the effort in question, and (c) management and other supervisory observation of employees designed to ensure the accuracy of employee labor records.

Secondly, there is a contradiction between what the auditors are recommending and what BSG has accomplished on the project. BSG is a start-up company with 10 employees. Your experts will, we hope, confirm that the scope of work in the grant is a hugely complex undertaking, combining **two** patient clinical trials, with all the related medical, engineering, legal, regulatory and organizational hurdles; and an FDA 510(k) application which has already been submitted a year ahead of schedule (over 600 pages long). These were daunting tasks for a company of our size. We knew how time-consuming these deliverables would be, and hired the appropriate team with these grant tasks in mind. Our progress report in Exhibit 2 demonstrates that despite these obstacles, we have delivered on our promised milestones, and achieved a ground-breaking clinical trial which is being recognized for its importance in the scientific community. Given the complexity and time-consuming nature of the operational tasks we have completed and the small size of our team, it simply impossible that this work could have been accomplished without a major commitment by our staff to the project. The recommended disallowances effectively say: "your staff have not been working at all or as much as you say on the project." We respectfully respond that given the small size of our company, the operational results achieved prove this impossible and the recommendations therefore unfair and overly harsh. We hope that when weighing these recommendations for disallowances HHS will take into account our excellent track record of results on the grant.

**Section III - Discussion of your preliminary findings**

Salary disallowances due to inadequate documentation

This subsection focuses on salary disallowances due to inadequate documentation. The following BSG employees were included in this group (note for privacy and competitive reasons, employee names have been redacted from this report. Each Employee Number refers to an employee who is identified in the Employee Key in Exhibit 3 to this report):

- Employee 1
- Employee 2
- Employee 3

- Employee 4
- Employee 5

For each employee we discuss reasons why the disallowance is unreasonable.

**Employee #1**

**1) Reasons why the disallowance is unreasonable**

In February and March 2011, 100% of Employee #1's monthly salary was charged to the grant based on BSG management's firsthand knowledge of Employee #1's grant-related activity, which activity we can demonstrate consumed 100% of Employee #1's BSG time and went far beyond normal working hours during the period in question. To disallow 100% of Employee #1's February and March 2011 salary is unfair and unduly punitive.

The main reason for hiring Employee #1 was to manage the medical portion of BSG's clinical trials funded by the NIH grant. The key element of our clinical trials for the grant is that Emergency Department patients have their brain signals recorded by means of *micro*EEG. This process of recording involves several steps. Surface electrodes housed in a fabric cap are applied to a patient's head, the quality of the electrode connections is verified and adjusted, and then recording of brain signals begins. The signals are sent in real time to an internet-connected laptop, from where they can be sent to a neurologist waiting to make a diagnosis.

To set up these recordings, we hired EEG technicians. Because none of the technicians had ever recorded in the Emergency Department setting, and Employee #1 is an Emergency Physician by training (see Exhibit 4 for his CV), he was designated as the person who trained the technicians to make these recordings. Before the hospitals involved would allow us to start our clinical trial with actual patients, we had to do extensive volunteer subject recordings to prove that we were capable of recording properly. Employee #1 was involved in all of the recordings from volunteer subjects during the February-March 2011 time period. Since the commencement of the patient trials in May 2011, Employee #1 has been supervising patient recordings by EEG technicians as well as interpreting the data for academic and scientific publications.
Importantly, Employee # 6 received regular updates from Employee #1 and the P.I. on his work during this time, interacted with Employee #1 during this time, reviewed his work during this time, and had direct firsthand knowledge of his clinical grant activity. Employee #6 estimated that Employee #1 was spending 100% of his time on the project because he knew Employee #1 was working full days and substantial overtime on preparing the EEG technicians for their upcoming role in the clinical trial. Given the abundance of time he was spending on the project that far exceeded a 40 hour work week, it therefore seemed very reasonable to assume his commitment was full time.

Prior to joining BSG in February 2011, Employee #1 served as a highly-skilled emergency physician. No one else at BSG had enough clinical and medical experience to run the medical component of the trials. In other words, it would have been impossible to develop the proper procedures and oversee the administration of the grant project in February and March without Employee #1 constantly at work during that period.

We are documenting Employee #1's February and March 2011 effort through the following items:

a) CV for Employee 1 (Exhibit 4) demonstrating his suitability to supervise clinical staff;

b) Email and attachment (Exhibit 5) from the Principal Investigator ("P.I.") on the grant regarding Employee #1's % commitment to the grant project;

c) Email and attachment from Employee #1 (Exhibit 6) showing during the period in question his work testing and credentialing EEG technician candidates for the clinical trial – the materials show what extensive screening and training had to take place by Employee #1 before the trial could begin;

d) Employee #1 carried overall responsibility for the administration of EEG's to enrolled patients. Over the course of the study, BSG enrolled 261 patients out of a total of 301 screened.

e) As a result of his research on the grant, Employee #1 has been an author of two scientific papers related to the project that were published in peer-reviewed scientific journals in 2011 and which cited support from BSG and the NIH grant (see Exhibit 7);

f) Employee #1 is listed as an inventor on three 2011 BSG patent applications that resulted from his work on the grant (see Exhibit 8). Note that due to the extensive length of the patent applications, we have provided only the first few pages of each of these applications. We would be happy to provide the full versions upon request:

g) Employee #1 is listed as lead author on a poster related to our project presented at the 2011 annual American Epilepsy Society meeting (see Exhibit 9).

h) Notes from a March 20, 2012 interview with Employee #1 where he confirmed that he has worked solely on the *micro*EEG project since his employment at BSG began in February, 2011 (see Exhibit 10).

As illustrated above, multiple records can confirm that Employee #1 devoted substantial effort to the grant in the February and March 2011 timeframe. To disallow all of his salary from this time period is therefore unreasonable and harsh.

**Employee#2**

**1) Reasons why the disallowance is unreasonable**

In May 2010, 23% of Employee #2's monthly salary was charged to the grant (although he spent almost 100% of his time working on the project) and the salary charge was based on BSG management's (and in particular, Employee #6's) firsthand knowledge of Employee #2's activity, which has always been 100% focused on the project in question. Because Employee #2 is based in the United Kingdom and travels from time to time to our NYC office, BSG only charged his time to the grant for the period spent working in the United States during a visit. This is the reason why only 23% of his time ended up being charged – while he was working more than this % on the grant project, that additional work occurred on foreign soil and we understood was therefore not eligible for drawdown.

Employee #2 is a co-founder of BSG. His sole responsibility was to oversee and coordinate the instrumentation associated with the grant project. Because Employee #2 is part of BSG senior management, Employee #6 had regular contact with him and was intimately familiar with his grant activity, which consisted of writing the software interface for *micro*EEG and supporting our *micro*EEG FDA application. Employee #2's sole project over the last several years was this NIH award; it would have been impossible for him to be working for BSG and doing anything else because he was not assigned to any other work and had no non-grant responsibility. We estimated Employee #2's hours based on the fact that we knew exactly how long his trip to the United States lasted and we knew that he had spent 100% of that time working on the *micro*EEG grant work.

Employee #2 (PhD) has 16 years of combined biomedical research and commercial experience. He has designed, manufactured, supported and managed the commercial deployment of complete systems for recording physiological signals.

We can document Employee #2's May 2010 effort through the following items:

a) interview notes with Employee #2 on March 19, 2012 which confirm that he spent 100% of the time charged to the grant from May 2010 on grant-related work (See Exhibit 11).

b) the interviews with BSG colleague who worked with Employee #2 on the project during the period in question (See Exhibit 11);

c) cv of Employee 2 (Exhibit 12);

d) Employee #2 is listed as an inventor on three 2011 BSG patent applications that resulted from his grant related work (See Exhibit 8):

As illustrated above, multiple records can confirm that Employee #2 worked on the grant in May 2010. To disallow all of his salary charges from this time period is unreasonable and unfair.

**Employee #3**

**1) Reasons why the disallowance is unreasonable**

Six hours of Employee #3's January 2011 hourly time was charged to the grant based on confirmation from Employee #3 and based on supervisory observation of Employee #3 which confirmed that six hours accurately represented his January 2011 effort.

Employee #3 was hired as an EEG technologist to do recordings of EEGs in the Emergency Department for our grant-funded clinical trial. Employee #1 and Employee #8 worked on the grant and, as Employee #3's supervisors, closely monitored his work and were present during his recordings in January 2011. Employee #3 was BSG's first EEG technologist and January 2011 was Employee #3's first month of work; therefore, Employees #1 and #8 needed to supervise his work very closely to make sure he was trained properly for eventually working with patients. They were thus deeply familiar with his work. Via e-mail to Employee #8 and cc'd to Employee #6 on January 20, 2011, Employee #3 summarized his hours for January as six hours in total. He included a breakdown of hours by day and he signed the email. Employee #1 and Employee #8 reviewed this e-mail and confirmed Employee #3's six hours

effort in an oral conversation with Employee #6, who had spoken with them to confirm Employee #3's hours before payment. Employee #3's contract stipulated he should be paid per hour, and thus BSG paid him $198 for January.

Employee #3 has no other role at BSG other than to serve as the EEG technologist for the grant. He has 25 years of experience recording EEG's in a variety of hospitals and neurology settings. The only reason BSG was recording EEGs in 2011 was to support the clinical trials which were part of the grant project. The only role Employee #3 could have been playing at BSG given his experience was to record EEGs; that is exactly what he did, and his supervisors confirmed that activity in January 2011.

We can document Employee #3's effort through the following items:

a) email from Employee #3 dated January 20, 2011, summarizing his hours for January 2011 work (Exhibit 13).

b) Exhibit 6 includes screening and credentialing work done by Employee #1 for Employee #3 that demonstrates his credentials as an EEG technician.

c) Email from Employee #8 concerning Employee #3's work from the time period in question (Exhibit 14);

d) Email from Employee #3 in January 2011 to Employee #6 and Employee #8 concerning his visit to the hospital in preparation for joining BSG as EEG technician (Exhibit 15).

Based on these records, we can confirm that Employee #3 worked on the grant in January 2011. To disallow all of his salary charges from this time period is unreasonable and unfair.

**Employee #4**

**1) Reasons why the disallowance is unreasonable**

For July 2010 through March 2011, all of Employee #4's BSG salary was charged to the grant in accordance with firsthand knowledge of Employee #4's grant-related effort by BSG management, including Employee #6. Employee #4 was hired as a Clinical Trial Coordinator, and BSG during this period was the Sponsor of only one clinical trial (this can be verified on Clinicaltrials.gov) – the clinical trial which is part of Specific Aim 2 of the grant in question. There is no other work a clinical trial coordinator could have done for BSG, and no one else in BSG who has ever coordinated a clinical trial. Therefore Employee#4 was clearly working on the clinical trial which is Specific Aim 2 of the grant. To disallow 100% of Employee #4's July 2010 through March 2011 salary is unfair and unduly punitive.

Employee #4 served as the grant's Clinical Trial Coordinator and has over seven years of experience as a clinical trial research manager and has been involved in multiple clinical Employee #4 is a published author in peer reviewed medical journals and has presented at numerous scientific and medical conferences. BSG hired Employee #4 because the grant project required BSG to run clinical trials for our *micro*EEG technology in hospital Departments. In order to run a clinical trial responsibly and according to FDA regulations, an experienced clinical trial coordinator is critical. BSG has no other clinical trials other than the trials funded by the grant, and that is precisely what Employee #4 was hired to coordinate.

Employee #4 had no other BSG responsibilities; the only work that Employee #4 would have been doing for BSG between July 2010 through March 2011 was the grant-funded clinical work. Employee #4 was uniquely qualified to coordinate the clinical trials funded by the and such coordination was a full time job. Given the enormous amount of administrative required, it would have been impossible to manage the grant project without Employee #4's constant and consistent supervision and coordination.

Employee #4's had regular communications with Employee #1 and Employee #8. All of these BSG individuals had close interaction with Employee #4 in the planning and conduct of the clinical trials funded by the grant during the July 2010 to March 2011 period. In addition, Employee #4 worked closely with the P.I. of the grant (See Exhibit 4). Employee #6 and other BSG management received regular updates from Employee #1 and Employee #8 and the P.I. on Employee #4's clinical trial coordination. Given that the trials commenced in April 2011 and proceeded smoothly through February 2012, it was clear to Employee #6 and other BSG management that Employee #4 was fulfilling Employee #4's full time duties to coordinate the trials during the period in question.

We can document Employee #4's effort through the following items:

a) Email and attachment (Exhibit 5) from the Principal Investigator on the grant regarding Employee #4's % commitment to the grant project;

b) notes from a March 20, 2012 interview where Employee #4 confirmed that Employee #4 has worked solely on the *micro*EEG project since employment at BSG in July, 2010 (Exhibit 16)

c) An email from the P.I. of the grant recommending that we hire Employee #4 and included Employee #4's CV (Exhibit 17). We note the evaluation is exclusively regarding the candidate's suitability as a clinical trial coordinator for the grant's clinical trial.

d) An email from our external clinical trial consultant, who is an experienced clinical trial monitor, who interviewed Employee #4 prior to the hiring and provided comments to Employee #6 on the applicant's suitability as clinical trial coordinator (Exhibit 18)

e) As a result of research on the grant, Employee #4 has been an author of a scientific paper related to the project that were published in peer-reviewed scientific journals in 2011 and which cited support from BSG and the NIH grant (see Exhibit 7);

As illustrated above, multiple records can confirm that Employee #4 worked on the project during the July 2010 to March 2011 time frame; indeed the clinical trials could not have commenced unless Employee #4 was working in a full time capacity. To disallow all of these salary charges from this time period is unreasonable.

**Employee #5**

**1) Reasons why the disallowance is unreasonable**

For the months in question, Employee #5's salary was partially charged to the grant in accordance with Employee #5's activity descriptions and BSG management's firsthand knowledge of Employee #5's grant-related activity.

Employee #5 is employed by BSG as an electrical engineering test technician, an area in which he has more than 10 years of experience. BSG's *micro*EEG technology needed extensive testing before it could be responsibly included in a clinical trial and submitted to the FDA for approval. Employee #5 was the only person at BSG who was qualified to do that testing. Employee #7 was Employee #5's direct supervisor and had direct knowledge of the projects Employee #5 was working on. Employee #7 provided to Employee #6 weekly updates and milestone schedules for the *micro*EEG hardware testing conducted by Employee #5. These communications designated and confirmed Employee #5's responsibility for testing the hardware, and BSG senior management was capable of following Employee #5's hardware testing activity, which we estimated never constituted less than 25% of Employee #5's overall BSG activity. The timesheets that were submitted by Employee #5 are consistent with management's understanding of Employee #5's grant activity and the timesheets confirm Employee #5's work on the grant as a tester of the *micro*EEG hardware.

To give an example of this, in Exhibit 19 we took a day by day look at the month of February 2011, which was one of the months in which Employee #5 had a timesheet with descriptions of his work rather than an hourly accounting. We charged 50% of his time in February to the grant (equivalent to $3,333.34), and the auditors have recommended that this entire amount be disallowed. This is also the largest monthly disallowance by the auditors for Employee #5's time. In Exhibit 19 we provide management comments on the corresponding project relating to each task Employee #5 recorded in his timesheet. We are not disputing that timekeeping could have been done better, but we feel this analysis demonstrates clearly that 50% of his time was indeed devoted to microEEG-related projects.

Moreover, we understand from Employee #5 that an OIG auditor conducted a phone interview with him on August 15, 2011, during which the auditor asked Employee #5 about how he spent his time on various projects, and he informed the auditor that on a typical week he was working 60-70% of his time on the *micro*EEG grant project.

We can document Employee #5's grant effort through the following items:

a) Exhibit 19 Employee #5 February 2011 Timesheet Analysis(see description above)

b) August 7 2010 email from Employee #7 to Employee #5 and others containing the operational plan for the clinical trial which indicates that a) Employee #5 was a member of the grant project engineering team and b) had specific responsibilities under testing microEEG (Exhibit 20);

c) an email dated March 18, 2011 from Employee #5 to Employee #7 & Employee #6 summarizing the results of Employee #5's many months of testing of the *micro*EEG system and a list of all bugs that were uncovered – finding bugs cannot be accomplished without extensive testing work. Bug list attached to his email can be provided to auditors in case of interest (Exhibit 21);

d) 36 pages of emails between Employee #5 and Employee #7 throughout the period in question detailing his involvement in testing *micro*EEG, as well as preparation for the *micro*EEG FDA application (another grant project deliverable) (Exhibit 22). We note that the activities described in these emails are time-consuming.

We can thus demonstrate that Employee #5 worked on the project during the period in question, and Employee #5's activity descriptions alone confirm his *micro*EEG testing for the grant. To disallow all of Employee #5's salary charges from this time period is unreasonable.

Modified timesheets

This subsection focuses on salary disallowances due to discrepancies that exist between the time documented and used for allocating time to the grant and the time originally documented and recorded by certain employees. The following BSG employees were included in this group:

- Employee 7
- Employee 8
- Employee 9

For each employee we discuss reasons why the disallowance is unreasonable.

In general we make the point that in the context of complex scientific research, an employee's supervisor often has the most reliable understanding of the employee's effort, and a particular understanding of how that effort benefits various projects. BSG management therefore reviewed timesheets in order to catch errors and omissions, and corrections to the labor records were made accordingly.

**Employee #7**

**1) Reasons why the disallowance is unreasonable**

Employee #7 was hired in July 2010 to ensure that the grant project was managed efficiently and on schedule. His CV and role are provided as Exhibit 23.

BSG Employee #6 had extensive knowledge of Employee #7's grant-related effort because Employee #7 and Employee #6 discussed the project every Monday during the period in question. Employee #7's time and effort on various projects was discussed at those meetings.

In this case we believe part (not all) of the disallowance is unreasonable. The part that is unreasonable is the costs that Employee #7 classified as indirect costs. Employee #7 was classifying as indirect costs work spent on preparing BSG infrastructure for the grant project. Examples of this work included ordering supplies, equipment and preparing our office for the grant team. Employee #6 classified these costs as direct, whereas Employee #7 did not. Employee #6 did so because the only reason these steps were made was to support directly our grant effort; without the grant project there would have been no work in these areas (we already had existing infrastructure for other projects in BSG which all predate the grant project). BSG management modified Employee #7's timesheets in order to reflect additional effort on the grant because additional segments of Employee #7's time were in fact allocable to the grant. In the context of management review of timesheets, management interpreted this time differently than Employee #7 and modified the time sheets to achieve the most accurate and fair allocation of Employee #7's salary to the grant in accordance with Employee #7's actual effort on the grant and management's direct supervisory knowledge of that effort. We acknowledge that we should have discussed this with Employee #7 at the time.

The auditors recommended a disallowance of $21,912.23 based on their analysis. We would

request that the erroneously posted indirect costs not be disallowed for the reasons explained This would lead to a reduction of disallowances by $16,273.63 (see table below), leaving a total disallowance of $5,638.60.

| Month | Total hours | Reclassified Indirect hrs | % of total hrs | Reclassified Salary |
|---|---|---|---|---|
| Jul-10 | 152 | 84.00 | 55% | $5,065.79 |
| Aug-10 | 176 | 78.00 | 44% | $4,062.50 |
| Sep-10 | 176 | 67.00 | 38% | $3,489.58 |
| Oct-10 | 168 | 55.00 | 33% | $3,000.99 |
| Dec-10 | 168 | 12.00 | 7% | $654.76 |
| | | | | $16,273.63 |

We can document Employee #7's grant effort through the following items:

a) a copy of Employee #7's curriculum vitae which shows his background's direct relevance to *micro*EEG development work (Exhibit 23);

b) interview notes with Employee #7 March 19, 2012 in which he confirmed that he had been working on grant project infrastructure for the hours allocated to indirect costs (Exhibit 24).

c) Employee #7 is listed as an inventor on the BSG patent applications that resulted from his grant work (Exhibit 8)

d) emails from Employee #7 related to the *micro*EEG project demonstrate his work on the project throughout the period in question (Exhibits 20, 21 and 22);

BSG management took seriously its responsibility to ensure that Employee #7's timesheets accurately represented his work on various projects. Management review of timesheets is designed to catch errors or omissions; Employee #6 caught Employee #7's omissions and adjusted the timesheets accordingly. We recognize that Employee #7 should have been required to re-sign the adjusted timesheet. BSG should not be penalized for management review that caught omissions that the employees concur with.

**Employee #8**

1) **Reasons why the disallowance is unreasonable**

Employee #8's cv is included in Exhibit 25. Employee #8 is responsible for the planning and execution of the grant-funded clinical trials, hiring EEG technicians for the trials, preparing grant-related IRB submissions, and similar duties. In addition as BSG's software programmer he was directly responsible for creating the "case management system" of microEEG – which takes EEG's recorded in the Emergency Department, sends them out to interpreting neurologists and returns a diagnosis. Without the case management system microEEG is

useless because a neurologist must be consulted in order to understand the significance of the EEG records. All of this effort is directly allocable to the grant project.

Employee #6 is extremely familiar with Employee #8's grant-related effort. Employee #8 has been from the beginning part of the BSG team of individuals who were planning and executing the clinical trial. Employee #6 and the PI and Employee #8 speak on a regular basis about current progress of the company, and in the course of these discussions, Employee #8's effort and activity was a regular subject.

We note that all of the time associated with Employee #8's salary disallowances is marked as "Admin" in Employee #8's original timesheet. We believe that this reflected a misunderstanding by Employee #8 as to what kinds of effort constituted general administration and what effort was allocable to the grant. There is no question as to whether Employee #8 worked on non-grant activity – he absolutely did not. Because of his background Employee #8 spent all of his time working to ensure the successful preparation and execution of our grant-funded clinical trials, and working on the case management system. Where Employee #8 allocated time to "administration," we are confident that that time was grant effort, and not unrelated "administration." The only responsibilities of Employee #8 were the grant-funded clinical trial preparation and planning. It is simply not possible that BSG would have employed Employee #8 to spend any amount of time on general administrative or clerical activity.
We interviewed Employee #8 on March 20 2012 and he confirmed that 100% of his time was spent on the microEEG project. We asked him what kinds of activities he included in the "indirect" cost category. He said that these included scheduling meetings for the grant project, planning the grant project, talking to clinicians in the grant project, researching information for the grant project, and finding vendors for the grant project. All of these activities in our opinion are clearly grant-related and not, as he indicated in his timesheets, indirect costs. We agree that we should have informed Employee #8 at the time of these issues and discussed the changes to his timesheets with him.

We can document Employee #8's grant effort through the following items:

a) Employee #8's CV which shows his background's direct relevance to clinical trial work (Exhibit 25);

b) Employee #8 Interview (Exhibit 26);

c) Email and attachment (Exhibit 5) from the Principal Investigator on the grant regarding Employee #8's % commitment to the grant project;

d) Employee#8 is listed as an inventor on the BSG patent applications that resulted from his work on the grant project (Exhibit 8);

e) As a result of his research on the grant project, Employee #8 authored a scientific paper related to the project that was published in a peer-reviewed scientific journal and which cited support from BSG and the NIH grant (Exhibit 7)

BSG management took seriously its responsibility to ensure that Employee #8's timesheets accurately represented his work on various projects. Management review of timesheets is

designed to catch errors or omissions; Employee #6 caught Employee #8's omissions and adjusted the timesheets accordingly. We recognize that Employee #8 should have been required to re-sign the adjusted timesheet. But Employee #8 agrees that, in light of his improved understanding of effort allocable to the grant, his original timesheets for the relevant period did not allocate as much effort to the grant as they should have, and he agrees with Employee #6's subsequent adjustments. BSG should not be penalized for management that caught omissions that the employees concur with.

**Employee #9**

**1) Reasons why the disallowance is unreasonable**

Employee #6 modified Employee #9's timesheet because Employee #9 omitted to record the full extent of his effort on the grant. In the context of management review of timesheets, Employee #6 caught those omissions and modified the time sheets to achieve the most accurate and fair allocation of Employee #9's salary to the grant in accordance with Employee #9's actual effort on the grant and management's direct supervisory knowledge of that effort.

Employee #9 serves as a junior laboratory technician for BSG. He is responsible for managing the laboratory, materials, and supplies for various projects, as well as testing equipment like microEEG to ensure proper functionality. Employee #9 had never completed timesheets in the past and as a junior staff member we believe he lacks perspective over what work belongs to what project.

We believe that these disallowances are unreasonable, however, we are unable to provide documentation to the contrary given the fact that the nature of his work is in the laboratory, and we think it is counterproductive to interview him given his lack of record keeping. We imagine and understand that this makes it unlikely that you will overturn the recommended disallowance, but hope you will consider these points nonetheless.

Health Insurance Reimbursement Disallowances

The draft audit report notes that "Bio Signal also claimed reimbursement of employee fringe benefit costs ($11,752) that were not reasonable for the performance of the award and were therefore unallowable." In an excel file provided to us by an OIG auditor we learned that this concerned the disallowance of BSG's repayment to employees working on the project of their health insurance costs. The excel file noted for BSG employee Employee #7:

*"Employee #7 had $7,899.97 in healthcare reimbursements. Employee #7 provided us with a copy of the health insurance card under his wife's name. The provided documentation is insufficient to prove that Employee #7 made monthly health insurance payments of $833. This documentation shows that he is covered under his wife's health insurance, but does not detail how much was paid towards the health insurance costs. We are disallowing $7,899.97 due to insufficient documentation."*

However we provided to the auditors after the exit conference a copy of Employee #7's wife's stub on which it was shown that she paid monthly health insurance premiums and we also forwarded to the auditors an email from Employee #7 explaining how he was covered under his wife's insurance policy and how he pays for health care costs. So it is not accurate that we only provided a health insurance card as documentation and we don't understand this comment. In

addition, as we explained to the auditors, the health insurance benefit in question was part of a contractual arrangement for fringe benefits with Employee #7, with the amount specified in his employee agreement (a copy of which is available for review). We view these payments as part the overall market rate compensation required to retain a person of Employee #7's caliber.

**Section IV - Corrective actions taken by BSG**

The purpose of this section is to summarize the improvements made by BSG since January 2011.

Background

BSG is an early-stage biotechnology start-up company. We were excited to win the grant award because it enabled us to fund clinical trials and product development that would otherwise have been beyond our means financially. We recognized the need for additional administrative infrastructure, and we consulted with our public accounting firm, Sheehan & Co, about measures to improve the financial administration of the company. This is a natural process as start-up companies make the transition to larger company.

Addition of Chief Financial Officer and Bookkeeping Assistant

In January 2011 BSG identified and hired a part time bookkeeping assistant who eventually became a fulltime BSG employee. Also, after considering various Chief Financial Officer candidates, we hired a full time Chief Financial Officer in April 2011. Our CFO has over 30 years of accounting experience in a variety of domestic and international businesses and has held the position of Chief Financial Officer in several companies before joining BSG. He also came recommended by our public accounting firm. His responsibilities include financial management of the NIH grant, inventory control, financial reporting, and management oversight and control of outside audits. The incorporation of the assistant and the CFO into BSG's infrastructure has led to significant improvement in financial administration and timesheet-related policy and procedure. Our A-133 Audit, which was completed in December 2011, is further evidence of our enhancements in these areas, and we are confident our next A-133 audit, to be completed in spring 2012, will be as well.

Administrative changes

There have been several changes in timesheet controls at BSG. The timesheet process has been formalized and streamlined. All employees are now using the same form, and all employees must sign their individual timesheet and keep a copy in their own files. Each employee is required to forward the original signed copy of the timesheet to their supervisor for approval. The supervisor is required to review each employee's timesheet. Once the timesheet is deemed correct, the supervisor is required to sign the timesheet and forward the original to the Accounting Department. This process is very important to BSG as timesheets form the basis for the company's time and effort recordkeeping for the *micro*EEG grant. The timesheets are used to accurately allocate payroll costs to the appropriate cost center in the BSG general ledger. These allocations are the most important part of the company's grant drawdown process.

Additionally, BSG has revamped its recordkeeping and payment approval process. As of April 1, 2011, all financial transactions are processed at the BSG office in Brooklyn. Once invoices are approved by the proper individual, all payments are processed at BSG using checks generated the BSG computer system. BSG no longer processes payments through Bank of America. This

change has enabled BSG to accurately control its cash disbursements. In addition, it has allowed BSG to properly maintain a file in Brooklyn so that all required financial records are close at

BSG also confirmed that it maintains complete files for all employees of the company. These files include, but are not limited to, employee payroll elections, employment contracts, and those documents required by law to verify employment eligibility. In addition, BSG has on file copies of all consulting and grant participation agreements.

**Section V - Conclusion**

The audit was a positive experience for BSG and an excellent opportunity for the company to interact with your audit professionals and take a fresh look at our recordkeeping practices. We learned from the experience and we are grateful for that.

BSG acknowledges that various salary charges to the grant in question were based on imperfect timesheets, and that timekeeping was not performed by employees as accurately as it could have been. We are a young company, growing quickly, and we recognize the need to have an appropriate financial administration in place in order to manage the NIH grant. We now have that administration in place.

We continue to disagree with the auditors' initial conclusions relative to the allowability of the salary costs in question. Although our timekeeping practices could have been better, we believe we can demonstrate that the employee salary charges in question were allocated in a manner that is consistent with each employee's grant-related effort, consistent with relevant documentation that supports the charges in question, and consistent with management and other supervisory observation of employees that was designed to ensure the accuracy of employee effort.

We're very proud of what BSG has accomplished operationally in the grant, and we would be happy to discuss this with you. Our corporate vision is to enable rapid brain monitoring anywhere at any time by anybody. We are motivated and excited that bringing this technology to market will have a positive impact on patient care and save health care costs. We are committed to executing that vision in accordance with the terms and conditions of our NIH grant.

We look forward to discussing this with you and answering any questions concerns you may have.
Respectfully,

Bio-Signal Group Corp.

John Gridley
Chief Executive Officer

cc: Mr. Glenn Richter, Audit Manager,
Department of Health and Human Services, Office of Inspector General

# APPENDIX B: NATIONAL INSTITUTES OF HEALTH COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

JUL 19 2012

TO: James P. Edert
Regional Inspector General for Audit Services, Region II, HHS

FROM: Director, National Institutes of Health

SUBJECT: General and Technical Comments on Office of Inspector General Draft Report, *Bio Signal Group Corp. Did Not Always Claim Recovery Act Costs in Accordance with Federal Requirements* (A-02-11-02009)

Attached are the National Institutes of Health's agency comments on the draft report, *Bio Signal Group Corp. Did Not Always Claim Recovery Act Costs in Accordance with Federal Requirements* (A-02-11-02009).

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-02-11-02009
NIH Technical Comments on OIG Draft Report A-02-11-02009

**GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT, ENTITLED *BIO SIGNAL GROUP CORP. DID NOT ALWAYS CLAIM RECOVERY ACT COSTS IN ACCORDANCE WITH FEDERAL REQUIREMENTS* (A-02-11-02009)**

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 require Bio Signal to refund $144,144 to the Federal Government (page 4).***

The NIH concurs with OIG's finding and corresponding recommendation regarding Bio Signal's costs claimed under the Recovery Act for NIH grant number 1RC3NS070658-01. We intend to recover the costs as recommended.

***OIG Finding 2: The OIG recommends that NIH ensure that costs charged to the Recovery Act reflect employees' actual effort and related salary not estimates (page 4).***

The NIH concurs with OIG's finding and would like to clarify the corresponding recommendation regarding Bio Signal's costs claimed under the Recovery Act for NIH grant number 1RC3NS070658-01.

We suggest that the recommendation be amended to read, "NIH should require Bio Signal to develop and implement policies for recording and distributing employees' time and attendance to properly account for costs claimed under federal grants."

***OIG Finding 3: The OIG recommends that NIH establish procedures for obtaining from employees documentation supporting health insurance premium costs (page 4).***

The NIH concurs with OIG's finding and corresponding recommendation regarding establishing procedures for obtaining from employees documentation supporting health insurance premium costs. However, we suggest that the recommendation be amended to read, "NIH should require that Bio Signal establish procedures and policies related to maintaining supporting documentation for accounting records (including health premium costs) claimed under federal grants."

**TECHNICAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT, ENTITLED *BIO SIGNAL GROUP CORP. DID NOT ALWAYS CLAIM RECOVERY ACT COSTS IN ACCORDANCE WITH FEDERAL REQUIREMENTS* (A-02-11-02009)**

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 i**, Par. 4: Please include the grant number (1RC3NS070658-01) for the 3-year, Biomedical Research, Development and Growth to Spur the Acceleration of New Technologies Pilot grant to be consistent with other American Recovery and Reinvestment Act (ARRA)-related OIG reports.

2. **Page 3**, Par. 2, Sentence 2 under "Salary Costs": Change to read as, "Pursuant to the Grants Policy Statement in effect at the time of the grant award (NIH Grants Policy Statement, 12/03), to be allowable under a federal award, salary cost must be based on a payroll distribution system that conforms with industry standards to support salary and wage charges, reflects daily after-the-fact reporting of hours expended on individual projects or indirect activities, and records both hours worked and absent. This information must also be certified by an Authorized Organizational Representative no less frequently than every pay period."