

Response Form for the Final Performance Review Report*

1. Name of Grantee: Albert Einstein Healthcare Network
2. Year of Grant: 2008 Formula Grant

A. For the overall grant, briefly describe your grant oversight process. How will you ensure that future health research grants and projects are completed and required reports (Annual Reports, Final Progress Reports, Audit Reports, etc.) are submitted to the Department in accordance with Grant Agreements? If any of the research projects contained in the grant received an “unfavorable” rating, please describe how you will ensure the Principal Investigator is more closely monitored (or not funded) when conducting future formula funded health research.

Grants funded through this mechanism receive the same level of oversight as our other research. Studies that involve human subjects research are overseen by the IRB and those that involve animal research are overseen by the IACUC. Our Office of Research and Technology Development follows up with investigators to ensure that the required reports are submitted to the Department of Health in a timely manner. Investigators who receive an “unfavorable” rating are not considered for future formula funded health research.

* Please note that for grants ending on or after July 1, 2007, grantees' Final Performance Review Reports, Response Forms, and Final Progress Reports ***will be made publicly available on the CURE Program's Web site.***

Project Number: 0862201

Project Title: E-Coaching to Support the Modification of Risk Factors of Metabolic Syndrome using Mediterranean Diet

Investigator: Figueredo, Vincent

B. Briefly describe your plans to address each specific weakness and recommendation in Section B using the following format. As you prepare your response please be aware that the Final Performance Review Report, this Response Form, and the Final Progress Report will be made publicly available on the CURE Program's Web site.

Reviewer 1:

1. One weakness noted was the dearth of process assessment that could provide further insights into how well the messaging and design of the intervention worked in this population. It is unclear whether the participants did follow through with regular submission of food and activity logs. If so, analysis of this information could shed light on which new dietary strategies were most likely adopted by these African-American women.

Response: Submission of food and activity logs was not as successful as we had hoped. Use of newly available technologies such as computer and phone applications (apps) make it easier for people to track food intake and exercise. Apps like www.myfitnesspal.com allow a person to track food intake and exercise and share that information electronically with selected persons. Incorporating use of apps for tracking food and exercise is suggested for future research.

2. Statistical analyses description: In the final report it would be helpful to state which statistical tests were performed to conclude there was not a statistically significant change, as well as including p-values in the results table.

Response: Baseline and 6-month data was presented as mean(sd). Statistical comparison used paired t tests. However, given the small number of subjects, the significance of these p values is suspect. A larger n will be required to produce statistically significant results.

3. Regarding dissemination of findings, it is recommended that the approach used and the findings be submitted as an abstract for presentation at a national or regional meeting. It would be particularly valuable to share what engaged the participants to remain in the project across the six months.

Response: We will investigate appropriate national or regional meetings to present the "lessons learned" and results of this study.

Reviewer 2:

1. The initial recruitment goal was not reached, despite its modest extent (20 participants). No adequate explanation is offered. The cost works out to over \$10,000 per subject, a rather expensive pilot with little to show for it.

Response: The fasting blood assays obtained during this study were expensive, but were useful to show participants how changes in diet can impact health beyond weight loss. This information was shared with the participants.

2. While perhaps unavoidable, having three PIs over the course of two years could not have had a good effect on the project, and this may be reflected in the results.

Response: It was unfortunate but unavoidable to have three PIs over the course of the two year study. The first PI did stay involved in the study through data collection.

3. Was no effort made to involve students or post-doctoral fellows?

Response: There were no students or post-doctoral fellows available to assist with this study,

Reviewer 3:

I would not recommend the use of waist/hip ratios in the next larger study.

Response: We agree with this recommendation.

C. If the research project received an “unfavorable” rating, please indicate the steps that you intend to take to address the criteria that the project failed to meet and to modify research project oversight so that future projects will not receive “unfavorable” ratings.

Response: N/A

D. Additional comments in response to the Final Performance Review Report (OPTIONAL):

Response: none

Project Number: 0862202

Project Title: The Use of High Flow Oxygen During ED PSA with Propofol:
A Randomized Trial

Investigator: Deitch, Kenneth

B. Briefly describe your plans to address each specific weakness and recommendation in Section B using the following format. As you prepare your response please be aware that the Final Performance Review Report, this Response Form, and the Final Progress Report will be made publicly available on the CURE Program's Web site.

Reviewer Comment on Specific Weakness and Recommendation (*Copy and paste from the report the reviewers' comments listed under Section B - Specific Weaknesses and Recommendations*):

Reviewer 1:

As stated in Section A, it would be more relevant to evaluate higher impact outcomes rather than transient hypoxemia.

Response: The reviewer is correct, and this is something we will consider in future research. It would be interesting to know if patients with respiratory depression and or hypoxemia during propofol sedation had neural system sequelae. I do think that getting this information would be challenging in a busy emergency department.

Reviewer 2:

None

Reviewer 3:

Their objective has only a moderate impact. They achieved their goals; yet I will be eager to see other similarly performed excellent studies that target adverse events other than transient hypoxia that readily respond to minimal intervention

Response (*Describe your plan to address each specific weakness and recommendation to ensure the feedback provided is utilized to improve ongoing or future research efforts*): We are currently doing advanced projects with Harvard and MIT to look at pre-apneic patterns associated with adverse respiratory events, by using complex computer algorithms to comb through multiple data streams such as SpO₂, ETCO₂, RR, HR, respiratory flow to identify patterns associated with apnea. We are doing similar work using rSO₂, or cerebral oxygenation to help identify patterns associated with apnea and terminal hypoxia. The goal would be to separate the signal, i.e., prediction of serious adverse respiratory events during deep sedation from sub clinical respiratory depression and hypoxia that is transient and will self resolve.

C. If the research project received an "unfavorable" rating, please indicate the steps that you intend to take to address the criteria that the project failed to meet and to modify research project oversight so that future projects will not receive "unfavorable" ratings.

Response:

D. Additional comments in response to the Final Performance Review Report (OPTIONAL):

Response: The support we received was hugely helpful in getting this project accomplished, and I just wanted to let the reviewers know how much I personally appreciate the backing...the work that we have done is in many ways early stage development for which large scale funding is out of reach, yet the work that we are doing has had significant impact on the state of knowledge in sedation in the ED. Thank you, and know that your backing was very much appreciated.

Project Number: 0862203

Project Title: Performance Evaluation of Spatial Normalization Protocols for Brains with Focal Lesions

Investigator: Kim, Junghoon

B. Briefly describe your plans to address each specific weakness and recommendation in Section B using the following format. As you prepare your response please be aware that the Final Performance Review Report, this Response Form, and the Final Progress Report will be made publicly available on the CURE Program's Web site.

Reviewer Comment on Specific Weakness and Recommendation (*Copy and paste from the report the reviewers' comments listed under Section B - Specific Weaknesses and Recommendations*):

Reviewer 1:

1. At the design stage of the study, it is important to anticipate many possible scenarios and plan accordingly how to handle them. In this case, I think the small sample size attained for the final analysis was 50% less than the original, and this might have had an impact on the conclusions.
2. The other issue was the use of a custom template (based on only 20 brains) for landmark implantation. Why not use a standard template generated from a large number of subjects and freely distributed with the software that you used to evaluate the spatial normalization procedures (SPM, FSL, etc.)? This way, other researchers could use the template with the landmark identified either to replicate your results or to do their own investigations.
3. Whenever one uses multiple raters to evaluate or do a manual task (such as landmark implant) the variability between the raters needs to be accounted for adequately. This can be addressed by including the variation induced by the different raters in the modeling of the data.

Reviewer 2:

It would be important to assure that the results are indeed published as a methodological paper.

Reviewer 3:

The product of the work is important but not transformative. While this is certainly a successful effort, more work is still needed to result in usable software and methods for basic and clinical science. Hopefully, the follow-on efforts will continue this work towards broad utility.

For the budget this was a success. Publications and successful grants were produced. Excellent collaborations were fostered. The hope is that follow-on work will result in approaches that significantly contribute to the analysis of brain images from patients with brain injuries.

Response (*Describe your plan to address each specific weakness and recommendation to ensure the feedback provided is utilized to improve ongoing or future research efforts*):

Reviewer 1, point 1: In the future studies, we will always include a contingency plan in the proposal stage of the project.

Reviewer 1, point 2: We proposed to use a custom template to generate a ‘symmetric brain.’ However, as the reviewer points out, it may also be a good idea to use a standard brain (e.g., MNI) to generate a ‘symmetric brain.’

Reviewer 1, point 3: We can include the raters’ variability in the model in the future analysis.

Reviewer 2: Funding for the research specialist who was supposed to work on the manuscript discontinued. However, we are actively seeking for funds to finish this manuscript.

Reviewer 3: We agree with the reviewer.

C. If the research project received an “unfavorable” rating, please indicate the steps that you intend to take to address the criteria that the project failed to meet and to modify research project oversight so that future projects will not receive “unfavorable” ratings.

Response:

D. Additional comments in response to the Final Performance Review Report (OPTIONAL):

Response:

Project Number: 0862204
Project Title: Development of a Haptic Virtual Environment
for Upper Limb Rehabilitation
Investigator: Jax, Steven

B. Briefly describe your plans to address each specific weakness and recommendation in Section B using the following format. As you prepare your response please be aware that the Final Performance Review Report, this Response Form, and the Final Progress Report will be made publicly available on the CURE Program's Web site.

Reviewer Comment on Specific Weakness and Recommendation

Reviewer 1:

1. There was some pilot testing of the system on college students, but the results and data were not provided in the review. The main criticism is that there was little, if any data provided to support that the project made progress.

Recommendation: In future applications, actual data should be presented to support the benefits, outcomes, utility and cost of the haptic VR system.

2. The progress report included a sentence that states, "We think of the applied stimuli as tactile joint torques that seeks to reduce the angular error."

Recommendation: In the future, the project would be improved if performance were defined, outcomes were presented and if there were a clear rationale to support why their VR system would have a beneficial effect on the outcome.

3. One of the main purposes for collecting pilot data is to support future grant submissions.

Recommendation: In the future, the project would have been strengthened if the aims for a future grant proposal were listed. If the objectives of the present project were met, then they would have corresponded with the aims of the future grant proposal.

4. There was no mention of license, patents or commercial development opportunities in the final progress report.

Recommendation: For the future, a provisional patent for the haptic VR system would be a positive outcome and protect the intellectual property of the developers for one year.

5. The team did not include a clinician with specific expertise in movement disorders.

Recommendation: For the future, one may argue that the team would be strengthened if engineers, psychologists, movement disorder scientists and clinicians all have input on the product.

Reviewer 2:

None

Reviewer 3:

1. There were no publications. I recommend publication in a peer-reviewed journal of data from normal subjects with this VR system. While it may be difficult to frame as a paper, the value of vibrotactile input could be tested, since the hypothesis is that such input adds to visual input in an important way.
2. No invention was pursued as a result of this research. I recommend discussion with intellectual property officials at the home institution regarding a potential patent for the technique developed.

Response

Reviewer 1:

1. We completely agree with the reviewer's comments about the need for actual data on the benefits of vibrotactile feedback. Given the limited budget, it was not feasible to design and build the full system, including purchasing the equipment, and also perform a full pilot test. However, this step was always planned and has since been completed. In future grants we will include a plan for data collection should funding allow.
2. Because we did not present any data, we felt a detailed discussion of how data would be analyzed was not warranted. We measured performance as average angular error (difference between performed movement and target movement at each joint) for each movement and each session. Later studies have shown that this angular error decreases more quickly with vibrotactile feedback than only visual feedback over several days of practice. In future grants, we will include a more detailed data analysis plan.
3. We agree with the reviewer, and had always intended to apply for future funding, although the specific timing of such an application was unknown given that pilot data on the system's effectiveness would be required. In future grants, we will more clearly specify these intentions.
4. The reviewer is correct that there is potential for commercialization, and therefore an additional potential positive outcome we did not include in the aims would be patent. In future grants, we will include this in the aims.
5. Inclusion of a movement disorder clinician was always planned for the first study with patients, a fact we failed to include because we did not plan to pursue this step under the proposed grant. In future grants, we will include more detail about future plans.

Reviewer 3:

1. We did not pursue publications until the system was tested in humans, which was not part of this grant. However, we have since published 2 conference papers (which is a standard means of publishing within engineering) and have one journal article in preparation. In future grants, we will include more detail about future plans.
2. See comment #4 for Reviewer 1.

C. If the research project received an “unfavorable” rating, please indicate the steps that you intend to take to address the criteria that the project failed to meet and to modify research project oversight so that future projects will not receive “unfavorable” ratings.

Response:

D. Additional comments in response to the Final Performance Review Report (OPTIONAL):

Response: