Response Form for the Final Performance Review Report – Lincoln 2010F*

1. Name of Grantee: Lincoln University

2. Year of Grant: 2010 Formula Grant

A. For the <u>overall grant</u>, 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. **[Response from Dr. Ayewoh, AVP/Chief Research & Sponsored Programs Officer, The Lincoln University]**

Our university grant oversight process is based on the attribution theoretical framework which posit that a designed and sustained outcome is a function of the positive internal locus of control of the principal investigator (PI); the positive external locus of control that is the centralized Office of Research and Sponsored Programs (ORSP) plus decentralized units of academic departments, academic colleges, fiscal affairs, etc, and the interaction effects between the PI and the staff of ORSP. Through positive interactions with the PI (to include mandatory post-award consultation with all key project personnel, ORSP Post-Award Officer, Grants Accountant/Fiscal Affairs, and Immediate Supervisor of PIs) within ten days of receipt of notification of awards, and periodic cyber and on-site sessions with PI, we can reasonably predict a high and significant level of PI compliance with the terms and conditions of the funded project.

To ensure that future health research grants and projects are completed and required reports are submitted to the Department in accordance with Grant Agreements, the Chief Research and Sponsored Programs Officer (or AVP) of ORSP will collaborate with the PI in developing action plans based on a Management by Objective (MBO) approach. The MBO will be inclusive of specific statement of work (SOW)/deliverables, specific and realistic time frame to successfully accomplish the plan of work, resources needed, and method of assessment and/or documentation of research outcomes. Components of the SOW will also include specified periods of post-award sessions by the PI with the AVP and with an appropriate Department Program Officer to update them on the nature and/or status of the funded projects. Such sessions will also assist the AVP and the Department Program Officer in addressing challenges faced by PI and development of creative approaches for successful resolution.

If any of the research projects contained in the grant received an "unfavorable" rating, the AVP will ensure that the PIs understand the practical implementation of the theoretical framework of attribution theorem. The MBO approach briefly discussed above will be employed to ensure that the PI clearly understands his/her role in designing and successfully implementing the funded project, and all expectations. The MBO will also ensure that the interactions between the PI and ORSP staff, and with the Program Officer are systematically monitored for desired outcomes.

* 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: 1085701
Project Title: Plasma Protein Biomarkers of
Chronic Obstructive Pulmonary Disease in African Americans
Investigator: Swinton, Derrick J.

B. Briefly describe your plans to address <u>each</u> specific weakness and recommendation in <u>Section B</u> of the Final Performance Summary Report using the following format. As you prepare your response please be aware that the Final Performance Review Summary 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)*:

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*):

Section B. Recommendations

SPECIFIC WEAKNESSES AND RECOMMENDATIONS

<u>Reviewer 1:</u>

1. Weakness: The PI did not have any peer-reviewed publication based on data collected in the research project.
   Recommendation: The PI needs to submit several articles for publication to the Journal of Biotechniques or *COPD: The Journal of Chronic Obstructive Pulmonary Disease*.

2. Weakness: Although data analysis will be performed in collaboration with Fox Chase Cancer Center, no detailed statistical data analysis methods were described.
   Recommendation: A health statistician could be hired or consulted as a research team member for statistical design and data analysis. Detailed statistical data analysis procedures would be described.

PI Response:
(1) A paper was not submitted during the initial round of funding to a peer reviewed journal because the PI needed additional time to validate the mass spectrometry technique used in the research project. That was noted in the Final Report and request for additional time and support to continue the research project. The PI submitted a proposal requesting additional time to validate the mass spectrometry technique and collect samples for the project. Additional funds were awarded by Lincoln University from their health research grant from the Pennsylvania Department of Health to extend the completion of the research. During the second year of funding, an article was submitted and accepted in the Journal of Proteome Research (Accepted

07-Jul-2013. Manuscript ID: pr-2013-00307u). The article discusses in detail the sample collection, ITRAQ technique, statistical analysis used to validate the mass spectrometry method, and an in depth discussion on the validity of the data by comparing different mass spectrometry instruments used in core facilities. Also the PI was concerned about the proprietary nature of the information generated by the research and concluded that delaying reporting the information to the public was warranted to protect the rights of the collaborators.

(2) The PI at Fox Chase Cancer Center and their respective in-house statistician completed the majority of the statistical analysis. In the future, the Statistician at both FCCC and LU will be enlisted to provide data analysis support. Lincoln University hired a statistician to support the research work undertaken in its Center of Excellence for Health Disparities.

Reviewer 2:

1. Weakness: Incomplete recruitment based on initial goals.
   Recommendation: Continue recruitment to meet stated goals.
2. Weakness: Lack of presentation of results and publication of results.
   Recommendation: Complete the study, including analysis of data when available. Prepare results for presentation at a national meeting and for submission of a manuscript to a peer-reviewed journal.
3. Weakness: Lack of follow-on funding.
   Recommendation: Complete the study and prepare an application for external funding.

PI Response:
(1) For clarity, the proposal attempts to communicate that a population of 10 Gold standard COPD patients will be enlisted to validate the mass spectrometry method. Upon validating the method, the method will be applied to analyze and screen for COPD Biomarkers in a population of African American Smokers participating in an ongoing research project conducted by the PI. The project's title is "Profiling Nicotine and its Metabolites in African American Smokers" which aims to understand the disproportionate susceptibility of smoking related diseases in African Smokers relative to Caucasian Smokers. This is standard protocol in these types of research projects whereby a method is tested on a small population of confirmed cases and then applied to testing the general population. Again, the PI assumes responsibility for not clearly articulating this approach in the proposal and Final Report.

(2) Results were published in the Journal of Proteome Research (Accepted 07-Jul-2013. Manuscript ID: pr-2013-00307u) and presented at the Association for Biomolecular Resource Facilities Annual Meeting (ABRF).

(3) Upon completing the first year of the grant, the LU and FCCC PI applied for and awarded funds from FCCC under its P20 grant. Also, the LU PI leveraged funds from his existing RIMI P20 grant to support the COPD project.

Reviewer 3:

1. There is no evidence of any progress on the project. Preliminary data should be obtained and presented, along with any difficulties encountered in achieving the specific aims.

2. The description of the research plans and methods is unacceptable. The plan needs to be significantly revised and strengthened.

PI Response:

(1) A paper was not submitted during the initial round of funding to a peer reviewed journal because the PI needed additional time to validate the mass spectrometry technique used in the research project. That was noted in the Final Report and request for additional time and support to continue the research project. The PI submitted a proposal requesting additional time to validate the mass spectrometry technique and collect samples for the project. Additional funds were awarded by Lincoln University from their health research grant from the Pennsylvania Department of Health to extend the completion of the research. During the second year of funding, an article was submitted and accepted in the Journal of Proteome Research (Accepted 07-Jul-2013. Manuscript ID: pr-2013-00307u). The article discusses in detail the sample collection, ITRAQ technique, statistical analysis used to validate the mass spectrometry method, and an in depth discussion on the validity of the data by comparing different mass spectrometry instruments used in core facilities. Also the PI was concerned about the proprietary nature of the information generated by the research and concluded that delaying reporting the information to the public was warranted to protect the rights of the collaborators.

(2) Again, for clarity, the proposal attempts to communicate that a population of 10 Gold standard COPD patients will be enlisted to validate the mass spectrometry method. Upon validation, the method will be applied to analyze and screen for COPD Biomarkers in a population of African American Smokers participating in an ongoing research project conducted by the PI. The projects title is "Profiling Nicotine and its Metabolites in African American Smokers" which aims to understand the disproportionate susceptibility of smoking related diseases in African Smokers relative to Caucasian Smokers. This is standard protocol in these types of research projects whereby a method is tested on a small population of confirmed cases and then applied to testing the general population. Again, the PI assumes responsibility for not clearly articulating this approach in the proposal and Final Report.

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: The PI acknowledges that the Final Report for the 2010 Formula grant did not adequately report the progress of the research project. The report lacked detail but for a specific reason. The reason for not submitting a more detailed report was because the PI did not want to release sensitive data and proprietary information without completing a more extensive study. Because the project is a collaborative project, the partners agreed to exercise caution in reporting

their findings until a publication and necessary documents protecting the intellectual property of the results was completed. To date, an article has been published in the Journal of Proteome Research that provides an exhaustive description of the research methodology and outcomes.

After discussing the project with the Program Manager at the Pennsylvania Department of Health, The PI acknowledges the oversight in not discussing the status of the project and Final report with the Program Manager prior to its submission and during the year. The conversation with the Program Manager discussing the reviews was very helpful and provided guidance whereby in the future the PI could use the information to submit a more detailed report without concern for compromising the integrity of the research, confidentiality agreements, and sensitive proprietary data.

The PI now understands the role of the Program Manager and his/her dual role as an advocate and manager.

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

Response:

Cited References –

(1) Title: "Easy Access to Mass Spectrometry at Multiple Core Facilities Operating TripleTOF 5600 and Orbitrap Elite/LTQ-Orbitrap Velos/Q Exactive Instruments"
Authors: Jones, Kelly; Kim, Phillip; Patel, Bhavinkumar; kelsen, Steven; Braverman, Alan; Swinton, Derrick; Gafken, Phil; Jones, Lisa; Lane, William S.; Neveu, John; Leung, Hon-Chiu; Shaffer, Scott; Leszyk, John; Stanley, Bruce; Fox, Todd; Stanley, Anne; Hall, Michael; Hampel, Heather; South, Christopher; de la Chapelle, Albert; Burt, Randall; Jones, David; Kopelovich , Levy ; Yeung, Anthony Manuscript ID: pr-2013-00307u.R1.