[Insert Date]

[Name]

Professor of [Specialty]

Duke University School of Medicine

RE:

Dear Dr. [Name]:

It gives us great pleasure to support you with the regulatory and quality assurance aspects of your project, [Short Title]. We look forward to working with you, FDA, and [Sponsor Name] to support the regulatory aspects of this project. We want to assure you the full support of our experienced team in the Office of Regulatory Affairs and Quality.

The Duke University Office of Regulatory Affairs and Quality (ORAQ) supports over 140 INDs/IDEs held by Duke investigators, and we oversee multiple pre-IND/pre-Submission meetings each year between Duke investigators and the FDA. We have been responsible for preparing and submitting numerous initial INDs, IDEs, and ITPs to the FDA. Through this work, we have gained extensive experience with the regulatory process for novel, investigational products. Furthermore, ORAQ led Duke’s efforts in preparing and filing a Biologics License Application and continues to manage the maintenance of this marketing application. This experience brings additional knowledge of Good Laboratory Practice and current Good Manufacturing Practice regulations and their applicability to early product development and clinical studies. We will gladly lend our expertise to ensure the utmost integrity and regulatory compliance possible for your work.

I am currently [Title] within the Duke University School of Medicine. In this role, I am responsible for providing support and guidance to investigators and study coordinators regarding the regulatory requirements relevant to their clinical research activities. I perform a variety of services including regulatory education, regulatory consultation, and support for regulatory submissions. I support Duke investigators and associated project teams with regulatory needs in a variety of therapeutic areas, including drugs, biologics, medical devices, and tobacco products. I have been involved in numerous meetings with the FDA, and my regulatory experience ranges from pre-clinical/early phase activities through regulatory application submission and maintenance.

You have assembled an impressive research team to perform the [Insert Description] studies described in your proposal, and it will be our pleasure to work with you in the future as you transition your product to direct testing in humans. We look forward to following up on our previous discussions and assisting you with [Insert Description]. Please don’t hesitate to contact me if any additional information is required at [Email].

Sincerely,

[Name]

[Title]

Office of Regulatory Affairs and Quality

Duke University School of Medicine