[Insert Date]

[Name]

Professor of [Specialty]

Duke University School of Medicine

RE: [Name of Funding Opportunity and FOA Number, if applicable]

Dear Dr. [Name]:

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.

In addition, ORAQ supports the Duke Health Institutional Review Board (IRB) by providing an FDA regulatory assessment for all Duke-initiated studies that will be reviewed by the IRB at a full board meeting. We review each protocol and provide the IRB with a regulatory framework for determining whether the study is subject to FDA oversight and if an IND or IDE application may be needed. Although ORAQ does not make the final determination on whether a study needs an IND or IDE, the IRB values ORAQ’s guidance when making the determination.

I reviewed the research strategy for the proposal submitted by Dr. [Name] for the [Award Name]. [Brief description of proposed clinical trial and medical products (drugs/devices/tobacco) that will be administered, used, or dispensed to participants].

[ORAQ regulatory assessment on whether the IND and IDE regulations apply].

Please do not hesitate to contact me if any additional information is required.

Sincerely,

[Name]

[Title]

[Email Address]

Office of Regulatory Affairs and Quality

Duke University School of Medicine