[DATE]

***[Address letter to the appropriate center below and delete those that do not apply]***

Center for Drug Evaluation and Research (CDER)

CDER-CoCRequests@fda.hhs.gov

Center for Biologics Evaluation and Research (CBER)

CBERBIMONotification@fda.hhs.gov

Center for Devices and Radiological Health (CDRH)

CDRH-CoC@fda.hhs.gov

Center for Tobacco Products (CTP)

CTP\_RIHSC@fda.hhs.gov

Center for Food Safety and Applied Nutrition (CFSAN)

CFSAN-CoCRequests@fda.hhs.gov

Center for Veterinary Medicine (CVM)

AskCVM@fda.hhs.gov

Dear FDA Reviewer,

I am writing this letter to request a discretionary Certificate of Confidentiality from the FDA for the below-described project.

**Descriptive Information *[When completing this section, please delete italicized instructions]***

Sponsor or Sponsor-Investigator Name or authorized representative *(e.g., the individual who takes responsibility for or initiates the clinical investigation)*:

Sponsor or Sponsor-Investigator or authorized representative Address (same as on file with FDA):

Sponsor or Sponsor-Investigator or authorized representative Email Address:

FDA Application Number, as applicable, *(e.g., IND/NDA/BLA/IDE/HDE/PMA/PMTA/ ITP; if exempt from submission of an investigational application, exclude this item*):

ClinicalTrials.gov Numerical Identifier (*if applicable; number provided upon registration on www.ClinicalTrials.gov)*:

Research Project Title:

**Assurances**

As requestor, I am engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected or used.

As requestor, I agree I am responsible for complying with requirements to protect the confidentiality of identifiable, sensitive information that is collected or used in biomedical, behavioral, clinical, or other research.

As requestor, I agree not to disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains. I also agree not to disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

As requestor, I understand that the identifiable, sensitive information collected by a researcher to whom a discretionary CoC has been issued, and all copies of such information, are subject to the protections afforded by the statute in perpetuity.

As requestor, I understand and agree that disclosure is permitted by the recipient of a CoC only when:

• Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

• Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

• Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

• Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

The signature provided for this request, if a facsimile or e-signature, represents a true and correct signature of the sponsor, sponsor-investigator, or that of an authorized representative, authorized to submit this request for a Certificate of Confidentiality and to make these assurances.

Sincerely,

[Signature of Sponsor, Sponsor-Investigator, or authorized representative submitting the discretionary CoC request]

[Printed Name of Sponsor, Sponsor-Investigator, or authorized representative]