Departmental Letterhead

<<Date of Submission>>

Food and Drug Administration

<Address>

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*For information on where to send studies, click* [*here*](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs) *(CDER) or* [*here*](https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/center-biologics-evaluation-and-research) *(CBER).*

INITIAL IND APPLICATION Serial 0000

Dear <FDA Division Director>:

Pursuant to 21 CFR 312, I am submitting an original, Sponsor-Investigator Investigational New Drug (IND) application.

The IND is being submitted to <short description of experimental treatment/drug and protocol> <If Pre-IND meeting was held, then insert text referencing the PIND# and date of the meeting>

Please find enclosed three (3) copies of an initial IND application submission. If you have any questions about the material included in this IND, please do not hesitate to contact me at <Name of Sponsor-Investigator with email and phone#>. Alternatively, you may contact my designee(s) <Name of designee(s) with email and phone #> who may interact with FDA on my behalf regarding this IND.

A letter of cross reference has been provided for IND <number> in support of the above referenced trial.

Thank you in advance for your consideration of this submission.

Sincerely,

<Signature>

<Sponsor, MD>

<Title>

<Address>

<Address>

<Address>

<Phone>

<Email>