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**Subject: Initial Investigational New Drug Application**

To Whom It May Concern:

I am hereby submitting an initial Investigational New Drug application (IND) for [Protocol Title] in accordance with 21 CFR 312.23.

The above protocol(s) is reviewed by the Institutional Review Board (IRB) at The Children's Hospital of Philadelphia. The CHOP IRB complies with the requirements set forth in CFR part 56 and is responsible for the initial and continuing review and approval of each study under this IND. As the Sponsor of this IND, I have and will continue to report changes in the research activity in accordance with the requirements set forth in the CFR part 56.

Thank you for your review of the IND application. If I can provide you any additional information, please do not hesitate to contact me at [email] or [phone].

Sincerely,

Sponsor-Investigator

Copy to: IND/IDE Support Program