Month ##, 2024

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WO71, G112

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**Subject: Single Patient Investigational New Drug Application**

To Whom It May Concern:

I am hereby submitting an Investigational New Drug (IND) application under section 505(i) of the Federal Food, Drug, and Cosmetic Act and in accord with 21 CFR 312 for DRUG for a single patient with DISEASE UNDER STUDY. We plan to treat this patient on DATE OF INTENDED TREATMENT.

The application contains the following:

* Please complete bulleted list of all documents to be included in the submission.

This study 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 this single patient IND protocol. Written informed consent will be obtained from the patient according to IRB guidelines using an IRB-approved ICF.

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

Sincerely,

IND Sponsor-Investigator

Copy to: CHOP IND/IDE Support Program