Month xx, 2024

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CBERDCC\_eMailSub@fda.hhs.gov

**Subject: IND xxxxxx, Serial #00xx – IND Withdrawal Request**

To Whom it may Concern

In accordance with 21 CFR 312.38, I am hereby submitting withdrawal of Investigational New Drug application (IND) number XXXXXX for xxINVESTIGATIONAL DRUGxx.

I hereby certify the following:

* All clinical investigations conducted under the IND have ended
* All current investigators and IRBs have been notified
* All stocks of the investigational drug have been returned to the drug supplier or otherwise disposed of in accordance with 312.59.

*Select the appropriate reasoning for the withdrawal and/or add a narrative as needed.*

Withdrawal of this IND is due to completion of the investigation(s). The final report for the investigation(s) conducted under IND XXXXXX is included with this submission.

Withdrawal of this Individual Patient Expanded Access IND is due to the patient being treated making sufficient recovery or moving on to another treatment therapy. The final report for the course of treatment for this patient under IND XXXXXX is included with this submission.

Withdrawal of this Individual Patient Expanded Access IND is due to the patient being treated experiencing disease progression and no longer responding to this treatment.

The final report for the course of treatment for this patient under IND XXXXXX is included with this submission.

Withdrawal of this IND is due to discontinuation of the investigation(s) after unforeseen safety concerns. The final report for the investigation(s) conducted under IND XXXXXX is included with this submission.

The following items, along with this Cover Letter, are included in this submission:

* Form FDA 1571 (for INDs) or Form FDA 3926 (For single patient IND)
* Final Treatment Summary
* Final Study Report

Thank you for incorporating these documents into this IND file. If you have any questions, you may reach me at XXname@chop.eduXX or XXphoneXX.

Sincerely,

xxNAMExx

Sponsor-Investigator

Children’s Hospital of Philadelphia

Copy to: IND/IDE Support Program