*IND Withdrawal or Closure Request: Cover Letter Template – On Sponsor-Investigator letterhead*

[Insert Sponsor or Sponsor-Investigator letterhead or address]

[Insert DATE]

[Insert FDA Project Manager and CDER/CBER Office/Division]

[Please refer to your letter from the FDA acknowledging the receipt of your IND application to identify the specific FDA contact person, and mailing address, to whom the Withdrawal Request and Final Report should be sent]

RE: IND Withdrawal Request for IND Number [Insert IND###,###]

Dear [Insert FDA Project Manager Name],

Enclosed please find a request to withdraw IND Number [Insert IND ###,###], for [Insert Product Name]. As of [DATE], the protocol was closed to patient accrual and on [DATE] a written request was sent to the reviewing IRB requesting termination of the study. The study terminated because [state reason why study was terminated].

Thank you for incorporating this Withdrawal Request into the respective IND file.

Sincerely,

[Insert Sponsor-Investigator Name]

[Insert Title]

[Insert Affiliation]

Enclosure: revised FDA 1571

Final Report