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**Template Letter**

**Form FDA 1572 Will Not Be Signed by Investigator**

Date:

Name of Sponsor/Contact:

Address 1:

Address 2:

City, Province:

Postal Code:

**RE: Request for Exemption from Requirement to Complete Form FDA 1572**

[PROTOCOL TITLE]

[PROTOCOL NUMBER]

Dear [name of Sponsor or contact]

I, Dr. [name of Principal Investigator] am the Principal Investigator for the above noted clinical trial. This protocol is being conducted under my supervision at Vancouver Island Health Authority.

In accordance with *Title* *21 Code of Federal Regulations (CFR) 312.120 Foreign clinical studies not conducted under an IND*, foreign studies and clinical sites need not be included under an Investigational New Drug (IND) Application and Investigators from non‐IND sites are not required to sign the Form FDA 1572. I have requested that the study Sponsor not include my clinical site under the IND, which means that I am not required to sign a Form FDA 1572. I understand that data from my site may be submitted to the FDA to support clinical investigates and/or marketing approval(s) in the United States of America (U.S.). The FDA is welcome to validate the data from my site through an onsite inspection.

With respect to the conduct and membership of the Institutional Review Board/Research Ethics Board, the [name of REB to be used as board of record] complies with:

* [Part C, Division 5 of the Food and Drug Regulations](https://laws-lois.justice.gc.ca/eng/Regulations/C.R.C.%2C_c._870/page-85.html#h-577812)
* [Part 4 of the Natural Health Products Regulations](https://laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/page-5.html#h-700807)
* [Part 3 of the Medical Devices Regulations](https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-7.html#h-1021976)
* [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)](https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf)
* Applicable local laws, such at [British Columbia’s Freedom of Information and Protection of Privacy Act](https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/96165_00)
* [ICH Guideline For Good Clinical Practice E6 (R2)](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)

I am committed to conducting the study in accordance with Canadian research requirements and with internationally accepted ethical principles. I agree to conduct the study in compliance with Health Canada regulations pertaining to clinical trials, Provincial law, the International Council For Harmonisation (ICH) Guideline For Good Clinical Practice E6 (R2), the Tri‐Council Policy statement (TCPS2) and the protocol. Further, I will sign the Qualified Investigator Undertaking (QIU) and provide necessary information for the Clinical Trial Site Information Form (CTSI).

If our site cannot be excluded or removed from the IND application, then we request the Sponsor obtain a waiver from IRB/REB requirements under section 21 CFR Part 56 before we sign the FDA 1572 form.

For additional information in support of this request, please refer to the FDA’s guidance documents:

* [Frequently Asked Questions – Statement of Investigator (Form FDA 1572)](https://www.fda.gov/media/78830/download)
* [Guidance for Industry and FDA Staff – FDA Acceptance of Foreign Clinical Studies Not Conducted Under and IND Frequently Asked Questions](https://www.fda.gov/media/83209/download)

Thank you,

[Signature of Investigator]

[Printed Name of Investigator]

Qualified Investigator