A picture containing company name

Description automatically generated  
  **Standard Operating Procedure**

|  |  |
| --- | --- |
| *SOP for Sponsors – Statement of Investigator, Form FDA 1572* | |
| Applies to: | Sponsors and NSH studies involving an IND |
| Sponsor: | VP Research, Innovation & Discovery |
| Issuing Authority: | *NSH Research Quality and Education* |
| Effective Date: | October 25, 2022 |

# Purpose

To guide and inform sponsors who have requested or have questions related to a Nova Scotia Health (NSH) investigator signing the form FDA 1572 for investigational drugs or biologics clinical trials overseen by the United States’ Food and Drug Administration (FDA).

# SCOPE

This document applies to sponsors or parties who are requesting that the form FDA 1572 be signed by a NSH Investigator.

# Background

Clinical trial research and the investigators involved in them in Canada are governed by Health Canada regulations. In Canada, drug trials must be conducted in accordance with ICH GCP E6; Health Canada regulations; Food and Drug regulations, Division 5: Drugs for Clinical Trials Involving Humans; and sponsor, institutional, and local research ethics board (REB) requirements. Together, these requirements assure clinical research in Canada is performed to a high standard.

Health Canada’s regulations are comparable regulations in foreign countries, including the USA *with the exception* of US Code of Federal Regulations Title 21, Part 56 and how it relates to the Institutional Review Board (IRB) or Research Ethics Board (REB).

# 

# ProCedure

1. Risk of NSH investigators signing the FDA Form 1572
   1. The Statement of Investigator, Form FDA 1572, is an agreement to assure the Sponsor that the Investigator will comply with the FDA regulations related to the conduct of a clinical trial of an investigational drug or biologic. Form 1572 is part of the application of US Sponsors for an IND application. Form 1572 requires investigators to attest that the study will be conducted under the requirements of FDA Title 21, Part 56:

*“I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation”.*

* 1. NSH Investigators cannot commit to the attestation in Form 1572 for the following reasons:
     1. The investigator does not oversee the NSH REB and therefore does not have the authority to assure the FDA that the NSH REB is compliant with foreign regulations.
     2. The NSH REB operates in compliance with the ICH GCP E6, Health Canada regulations, and the Tri-Council Policy Statement. Canadian REBs are not governed by foreign regulations are therefore not required to be compliant with the FDA requirements for the IRB. Specifically, NSH’s REB is not in compliance with the REB requirements stated by the FDA.

1. Recommendations to Sponsors
   1. NSH requests that Sponsors do not list NSH on the IND and therefore there is not a need for the Investigator to sign From 1572. As per the FDA, Canadian Trial sites do not need to be included under the IND (21 CRF 312.120). Canadian sites can participate in a foreign IND study and contribute data to be used in support of the IND. The FDA’s 2010 Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs clarifies that excluding foreign sites from the IND will not affect the Sponsor’s ability to submit the data to the FDA, if the study is conducted in accordance with the laws and regulations of the country in which the research is conducted.
   2. NSH’s practice is to advise Investigators to NOT sign Form 1572. The trend in Canada is for Canadian Sites and Investigators to request to not be included in the IND or sign the Form 1572. This practice is expected to become more consistent in the future.
   3. If NSH is listed on the IND and the Investigator has signed Form 1572, there are two options for the Sponsor:
      1. The Sponsor can have NSH removed from the IND; or
      2. The Sponsor can seek a Waiver from the FDA for the NSH REB/IRB. Failure to obtain a waiver leaves NSH and the Investigator in a position of non-compliance. The FDA may waive any of the IRB requirements for specific research activities for classes of research activity otherwise covered by the IRB regulations when alternative mechanisms for ensuring protection of human subjects’ rights and welfare are acceptable. The requirements for this are outlined in the FDA information document:

<https://www.fda.gov/media/78830/download>

1. Canadian assurance in protecting rights and welfare of human subjects:
   1. Per Health Canada, Canadian REBs must attest that:
      1. The membership of the REB complies with REB membership requirements, defined in part C Division 5 of the Food and Drug Regulations; and
      2. The REB carries out its functions in a manner consistent with Good Clinical Practice; and
      3. The REB has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the Qualified Investigator named above at the specific clinical trial site. This approval and the views of the REB have been documented in writing.
2. Summary
   1. As a foreign site, Nova Scotia Health is not required to be listed on an IND nor are Investigators required to sign Form 1572.
   2. If NSH is included on the IND and the Investigator signs the Form 1572, the sponsor must request a waiver for the REB/IRB so that NSH can participate in the study.
   3. Without the FDA Waiver, NSH cannot be in compliance with the FDA regulations.
3. FAQ
   1. Can Canadian sites still participate in a US IND study without signing form 1572? **YES**
   2. If form 1572 is not signed, can the data from the NSH site be used toward the IND? **YES**
   3. Will the other documents (QIU, STSI, signed protocol, contract, etc.) cover the requirements needed by the US? **YES**

# References

1. Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs FAQs – Statement of Investigator (Form FDA 1572)

<https://www.fda.gov/media/78830/download>

2. Good Clinical Practices, Government of Canada, Health Canada, Food and Drugs Regulation

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices.html>

\* \* \*