

CLINICAL RESEARCH QUEBEC

Memo

To: Sponsors of clinical trials regulated by the FDA
Date: May 9, 2022
Re: FDA Form 1572 – Requirements for Canada and Quebec

Dear Sir/Madam,

We would like to draw your attention to the Canadian and Quebec requirements regarding the signing of the FDA 1572 form, as concerns clinical trials. Signing the FDA 1572 form is a regulatory obligation and thus constitutes a contractual requirement in all agreements involving United States sites participating in clinical trials regulated by the U.S. Food and Drug Administration (FDA). However, study sites located within the Quebec Health and Social Services Network (*Réseau de la santé et des services sociaux du Québec*) are to be exempted from this requirement, as well as from requirements relative to the operating procedures and composition of Research Ethics Boards as stipulated in the document “*Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs – Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*”.

To maximize compliance with requirements, study sponsors should proceed according to one of the two (2) scenarios below:

- 1. If the Quebec study site(s) are listed in the Investigational New Drug Application:**
Submit a request for exemption from requirements pertaining to the signature of Form FDA 1572 and from requirements pertaining to the operating procedures and composition of Research Ethics Boards for the site(s) in question (21 CFR Part 312.10).
- 2. If the Quebec study site(s) are not listed in the Investigational New Drug Application:**
As clinical trials in Canada must be conducted according to principles set out in the ICH E6 Good Clinical Practice (GCP) Guideline, and because Canadian study sites are still subject to possible inspection by the FDA, the requirements pertaining to the signature of Form FDA 1572 and to the operating procedures and composition of Research Ethics Boards no longer apply to the site(s) in question (21 CFR Part 312.10).

In either case, qualified investigators at sites located in the Quebec Health and Social Services Network should no longer sign Form FDA 1572.