

Nagano forms

Where can I find Nagano forms?

- When a new project is created, a “**Form 11**” (or one of its different versions) is created.
- When a project is approved, the follow-up forms become available to the investigator.
- Certain follow-up forms are added to the project’s file by the REB only when required.
- To create / add a new form :
 - Select a project in the “My Projects” segment and click on the “forms” button:
 - On the high right, click on the button to select a form;
 - Click on the “Submit” button to submit the form. If it is grey (), this means that required fields have not all been filled out.

Which forms do I use?

Number and name of form* :	Use :
F1 - Amendment to an approved study	Submit an approval request for an amendment / modification to an approved research project. For guidance on what must be submitted as an amendment, refer to the REB’s Standard Operating Procedures on “Ongoing REB Review Activities.”
F2 - Additional information and/or miscellaneous communications	Transmit all other additional information or correspondence that cannot be transmitted via another form.
F3a - Reportable Local Serious Adverse Event (i.e. occurring in a center under the jurisdiction of the MUHC REB)	Report serious adverse events (SAE) that have occurred in the institution or in another institution in the health and social services network under the jurisdiction of the MUHC REB for the multicentre projects as per the MSSS’ framework.
F3b - Other reportable events (ex. deviation, privacy breaches, complaints)	Report other events for which declaration is mandatory (deviation, privacy breaches, complaints, etc.).
F6 - Notification of change in Study Status	Report a change of status for a research project.
F7 - Additional information following study migration	This form is created the first time you complete a follow-up form (for the projects submitted before Nagano was launched). It allows you to update the information on the project registered in the system.
F9 - Annual renewal submission	Request an annual re-approval of the research project (form created by the REB when required).
F10 - Termination Report	Report the end of a research project .
F20 – PI responses to REB requests	Receive and transmit responses to the conditions and requests for precisions raised by the REB.
F22 - Submission of translated study documents	Submission of translated study documents
Specific forms for multicentre projects (2 centres and + in the RSSS, following MSSS mechanism):	
F1MP - Request to convert to MC or add a new site	a) Convert a multicentre study (2008) or a single-centre study into a multicentre project as per MSSS 2014 framework. b) Add an institution to a multicentre project.
F10MP - Notice of site closure within a multi-center project	Report the closing of a site during the conduct of a multicentre project.