

Step #	Step	Responsibility	Action	Recipient	Document	Article - "cadre de reference"
1.1	Submit the appropriate ongoing review form (External site PI or ALL SITES)	EXT. Coordinating PI	Submit the appropriate ongoing review form (ex. amendment, deviation, etc.) : <ul style="list-style-type: none"> When it applies to the external site only OR When it applies to all sites, including the Network ICF and any other documents (Fr, En, Track changes & clean), as applicable 	External reviewing REB	<ul style="list-style-type: none"> Ongoing review form of the rREB Network ICF version and all other documents (Fr & En.) as applicable 	12.2, 12.3
1.2	Submit the appropriate ongoing review form (MUHC site only)	MUHC PI	Submit the appropriate ongoing review form (ex. SAE, deviation, etc.) : <ul style="list-style-type: none"> When it applies to the MUHC site only 	External reviewing REB	<ul style="list-style-type: none"> Ongoing review form of the rREB 	12.2, 12.3
2	Approval of ongoing review request by the external rREB	External reviewing REB	<ul style="list-style-type: none"> Approves the ongoing review request, the network ICF and other documents (Fr., En.) as applicable and provides their decision: When it concerns the MUHC only When it applies to all sites, including the Network ICF and all modified documents (Fr, En, Track changes & clean), as applicable 	MUHC PI	<ul style="list-style-type: none"> Ext rREB Approval Network ICF version and all other documents (Fr & En.), as applicable 	12.4
3	Provides the approval of the ongoing review	External reviewing REB	<ul style="list-style-type: none"> Approves the ongoing review request, the network ICF and other documents (Fr., En.) if applicable and provides a decision: When it concerns the MUHC only When it applies to all sites, including the Network ICF and all modified documents (Fr, En, Track changes & clean), as applicable 	MUHC PM	<ul style="list-style-type: none"> e-mail Approval of the external rREB Network ICF version and all other documents (Fr & En.), as applicable 	12.4
4	Distribute the ongoing review approval	External reviewing REB	Forwards the rREB approval of the ongoing review notice and the approved Network ICF and other documents (Fr & En) as applicable	Sponsor	<ul style="list-style-type: none"> Approval of the external rREB Network ICF version and all other documents (Fr & En.), as applicable 	12.4
5	Submit the external rREB's approval of the ongoing review request and the local MUHC version of the ICF and other modified documents (Fr. & En, TC and clean) as applicable	MUHC PI	Submits in Nagano all approvals of ongoing review requests obtained from the external rREB, as well as the network and local ICF versions and other related documents (Fr. & En, TC and clean) by using the F2MEO, F9MEO or F10 forms.	MUHC PM	<ul style="list-style-type: none"> F2MEO, F9MEO, F10 Network ICF version and all other documents (Fr & En.), as applicable MUHC local ICF version and other modified documents (Fr. & En., TC, clean) 	12.5
6.1	Approval of local MUHC ICF and other modified documents (Fr. & En.)	MUHC PM	Approves Nagano F2MEO or F10 notifications and validates the local MUHC ICF version and other documents (Fr. & En.)	MUHC PI	<ul style="list-style-type: none"> F2MEO, 10 	12.5
6.2	Approval of ongoing authorization (Specific to F9MEO)	MUHC PM	Completes, submits and approves a F9MEO form, i.e the notification of ongoing authorization form, once the annual renewal notice is received from the external rREB, (if the MUHC PI has not already done so (step 6.1))	MUHC PI	<ul style="list-style-type: none"> F9MEO 	12.5

7	Shares the local MUHC ICF version and other modified documents (Fr. & En., TC, clean)	MUHC PM	Forwards the rREB approval of the ongoing review notice and the approved Network ICF and other documents (Fr & En, TC & clean) as applicable	External rREB	<ul style="list-style-type: none"> • F2MEO • MUHC local ICF version and other documents (Fr. & En., TC, clean) 	12.5
8	Forwards the local MUHC ICF and other modified documents (Fr. & En.)	MUHC PI	Forwards the rREB approval of the ongoing review notice and the approved Network ICF and other documents (Fr & En) as applicable	Sponsor	<ul style="list-style-type: none"> • F2MEO, F10 approved • MUHC local ICF version and other documents (Fr. & En.) 	12.5
9	REBA	External rREB	Updates and forwards the REBA if applicable	MUHC PI, MUHC PM	<ul style="list-style-type: none"> • REBA 	8.6
10	Submit an amendment to an aspect regarding the MUHC feasibility	PI/coordinator MUHC	Communicates the nature of the modifications by e-mail	MUHC feasibility evaluation	<ul style="list-style-type: none"> • E-mail 	No applicable article in the cadre de référence du MSSS
11	MUHC authorization	MUHC feasibility evaluators	<ul style="list-style-type: none"> • Reviews and approves the feasibility aspect for which s/he is responsible • Forwards the relevant O.D. (contract, pharmacy, ...) as applicable 	MUHC PI	<ul style="list-style-type: none"> • E-mail • O.D. in Nagano if applicable (contracts, pharmacy, ...) 	No applicable article in the cadre de référence du MSSS

rREB= Reviewing REB, the REB responsible for approving and monitoring the research project at all participating institutions in QC