Multicentre Process – Research Conducted by a Private Sponsor

Authorization of a Clinical Trial Conducted in More Than One Institution

Clinical Trials Quebec™

CATALIS MD

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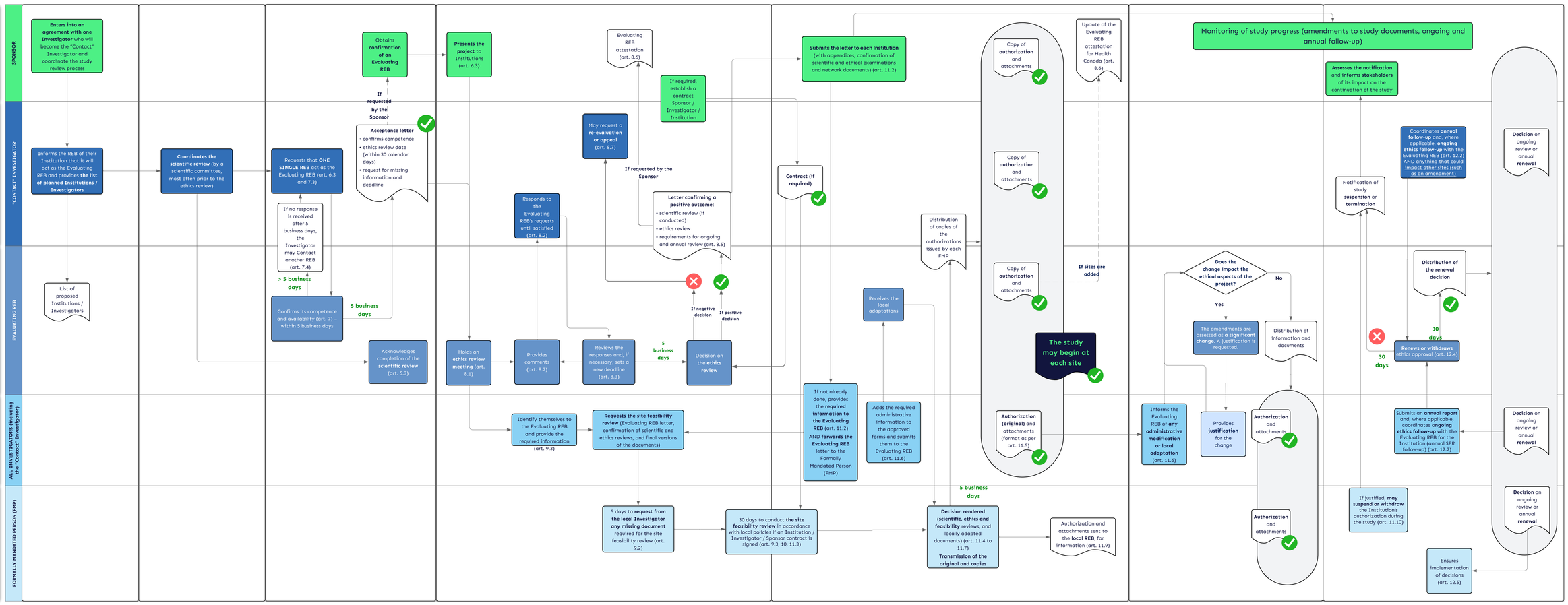
	Identification of the "Contact" Investigator	Scientific review	Confirmation of the REB's competence and acceptance	Ethics review and site feasibility review	Authorization for each site	Amendments and modifications	Ongoing follow-up and annual renewal
Coordinates authorizations and communications between study sites, in collaboration with the "Contact" Investigator.							
Primary intermediary between the Sponsor, the Evaluating REB and the Investigators at each Institution.							
At the request of the "Contact" Investigator, acts as the sole Evaluating Research Ethics Board (REB) for all sites.							
Responsible for the conduct of the study at their Institution and for reporting on its progress.							
Authorizes the conduct of the study and ensures the follow-up of the authorization within the Institution.							



Summary of the different steps

The **Sponsor** identifies the **"Contact" Investigator**, who then obtains a letter from their REB that includes the following:

- agrees to act as the **Evaluating REB**;
- confirms its competence;
- announces an ethics review date (within 30 days);
- requests any missing information and specifies the submission timelines.

This request for acceptance may be submitted to only one REB at a time.

The **"Contact" Investigator** initiates the scientific and ethics reviews of the project.

The **Sponsor** connects the already identified **sites** and **Investigators** and provides them with all necessary information. Each Investigator requests that the **Formally Mandated Person (FMP)** of their Institution carry out the site feasibility review of the study within 30 days.

If necessary, a contract is established between the **Sponsor**, the **Investigators** and the **Institutions**.

During this period, the **Evaluating REB** conducts the ethics review of the study, in collaboration with the **"Contact" Investigator**, within a maximum of 30 calendar days. This review exempts each site from conducting its own ethics review. If the evaluation is positive, the Evaluating REB issues a letter including:

- confirmation of the ethics review;
- confirmation of the scientific review (if conducted);
- the appendices and approved documents;
- the requirements for ongoing follow-up and annual reporting.

The **Sponsor** communicates the Evaluating REB's decision and the relevant documents to the Investigators at each study site.

If they were not previously identified, these sites initiate the site feasibility review.

They adapt the administrative portion of the documents approved by the Evaluating REB to their site.

Based on the results of the ethics, scientific and feasibility reviews, the execution of a contract (if applicable), and compliance of the local adaptations of the approved documents, the Formally Mandated Person (FMP) may authorize the conduct of the study at their site, and the study may begin.

The **Sponsor** is informed of the progress of the study, notably through the **Evaluating REB**'s decisions and authorizations in the following circumstances:

- **local** administrative modifications to approved administrative documents;
- ongoing follow-up of events impacting the study (SER, deviations, risks);
- annual renewal of the ethics review.

ADDITIONAL NOTES:

- This document is an adaptation of the Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l'autorisation d'une recherche menée dans plus d'un établissement (Reference Framework for Public Institutions of the Health and Social Services Network Authorization of Research Conducted in More than One Institution) (2016). It is a guidance document and does not replace the MSSS Reference Framework (CdR).
- For the sake of clarity and readability, the addition of a **sub-study** has not been addressed. This process generally follows the authorization of a new study (see the CdR).
- Although the multicentre framework does not place specific emphasis on the following aspects, it is useful to consider that:
  - Investigators should have easy access to the Evaluating REB.
  - Careful attention should be paid to study budgets during contract negotiations with Investigators and Institutions.

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