

Guidance Document	Application Guidelines for Multi-phase Research and Open Label Extensions
Effective Review	HSREB
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The Health Sciences Research Ethics Board (HSREB) reviews research protocols via an online application in the Western Research Ethics Management system. This allows the protocol as it was conceived to be reviewed but also ensures that important elements around procedures, data handling, risks, recruitment, and consent are specifically outlined as requested in the application. WREM also ensures complete information is given to the HSREB and organizes study documentation for review and approval.

For multi-phase research or research involving multiple methodologies and or populations, the distinction of when one, versus multiple, applications are required can be nuanced. Certainly, a separate WREM application is required for each protocol. **One application cannot accommodate multiple protocols.**

For non-clinical research with a single protocol, it is acceptable to seek approval for a single protocol outlining multiple phases or components. However, it is also acceptable and often preferable to submit a separate WREM application for each phase. This facilitates the application being clear and thus a timely review. When a researcher submits multiple WREM applications for a related course of study, they *can* be reviewed at the same time and measures are taken to link the applications so that the context is provided for reviewers. When at all possible, a single Ethics Officer is assigned to all related files even if they are not submitted at the same time.

When considering whether or not to submit multiple applications, please consider the burden on the researcher to explain separately and in an itemized way the procedures, data handling, risks, population, and consent for EACH component. This can be challenging, but not impossible, in one application. **If each phase is not sufficiently clear in the initial submission or populations are deemed to require different risk-benefit considerations, the HSREB can request separate applications. These may need to be reviewed consecutively rather than concurrently.**

Similarly, amendments that propose an additional protocol or are of a scope deemed to be outside of the initial objectives of a study will require a new WREM application.

Considerations specific to Open Label Extension Studies (OLEs)

Pharmaceutical research often includes an open label extension (OLE) study. This occurs when patients participating in double blind placebo-controlled trials of new medications are invited, on completion of the initial trial, to take the study drug for some further period. Patients are openly given the active substance at this stage, regardless of their assignment in the initial trial.



If an OLE is integrated into the initial trial design within the same protocol for initial review, both/multiple phases can be submitted as one application. **However, there MUST be a separate Letter of Information and Consent for the OLE.**

However, if the OLE is not planned at the time of the initial application, for the purpose of HSREB review/approval, the main study and OLEs are two separate studies and should be submitted separately.

OLE studies generally have different objectives, methodology, benefits and risks, participant populations and recruitment processes, and different information/consent documentation

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