A frequent feature of pharmaceutical research is the open label extension study, in which 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. The purpose of the Open Label Extension study is to assess long term safety issues, while the drug is waiting for final regulatory approval.

Open Label Extension Studies (OLEs) are different from the primary study and require new submission of a separate protocol form. They are reviewed and monitored separately from the primary study. OLEs are not revisions to or extensions of existing studies.

The protocol for the OLE should not be submitted until the OLE is within 6 months of its anticipated start date. If the OLE is anticipated to start within 6 months of the primary study, the OLE protocol may be submitted at the same time as the primary study, but it must be a separate submission.

OLE studies generally have different objectives, methodology, benefits and risks, subject populations and recruitment processes, and different information/consent documentation requirements. The HSREB examines OLE studies carefully because individual participants may be invited to participate in the OLE without knowing their treatment status in the primary study (e.g. active drug or placebo), and before aggregate data about efficacy and safety have been fully analyzed. This means that subjects previously doing well on placebo or low doses of the drug will be enrolled in the OLE on active medication and often at a higher dose than they were taking previously. In addition, the HSREB is concerned about the possible undue inducement of continued access to free medication particularly if it is offered at the beginning of the primary study.

These issues are of sufficient concern to require the protocol, SAEs and other issues associated with the OLE to be reviewed and monitored separately from the primary study.