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Guidance Document	Guidelines for Open Label Extensions
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Pharmaceutical research often includes an open label extension 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.

For the purpose of HSREB review/approval the main study and Open Label Extension Studies (OLEs) are two separate studies and should be submitted as separate submissions.

OLE studies generally have different objectives, methodology, benefits and risks, participant populations and recruitment processes, and different information/consent documentation requirements. There is also concerns regarding participants who had been randomized to placebo in the RCT who will, in the OLE, be subjected to open label medication. There is a greater need for monitoring at first dose(s). 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 participants previously doing well on placebo or low doses of the drug will be enrolled in the OLE on active medication and the participant may be given a higher dose then they were previously taking.

The HSREB is concerned about the possible undue influence to participate in the clinical trial with the understanding of potential 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.