







**Option 3: Lead submission pathway.**  
**The initial submitting site is responsible for all PICF updates.**

**1.** The lead submits a master PICF that contains specific inclusions for all sites participating in the project. The inclusions appear as stacked 'placeholders'.



**2.** The lead is responsible for coordinating and updating the master PICF on behalf of all additional sites. Throughout the duration of the study, the HREC reviews the master PICF as one complete document.



**3.** After the study has been approved, an additional site joins the project.



**4.** The additional site is reviewed by the HREC as being suitable to participate in the trial.



**5.** The additional site waits for the lead to update the master PICF with their site specific inclusions (if applicable). *Note: already approved sites do not need to update their site specific PICFs as changes to the master are only relevant to the newly commencing site.*



**6.** The lead updates the master PICF to include information from the additional site.



**7.** The updated master PICF is reviewed and approved by the HREC.



**8.** Trial activities may commence at the additional site.