1. **Has the FTIH/Phase 1 clinical trial commenced already?**

If **YES**, please provide the following information with your ethics application

|  |
| --- |
| **Status of trial** |
| Country/countries where the trial has commenced |  |
| Regulatory authority approval e.g. FDA IND number, evidence of approval to proceed, version and date of approved protocol |  |
| **Status of participants** |
| Number on FTIH treatment |  |
| Number off FTIH treatment |  |
| For participants off treatment: |
| Number completed treatment per protocol |  |
| Number stopped treatment per protocol. Provide reason(s) |  |
| Number stopped treatment for other reason. Provide reason(s) |  |
| **Safety information** |
| Have any urgent safety measures been implemented? If yes, provide description of event(s) |  |
| Have any significant safety events occurred? If yes, provide description of event(s) |  |

If **NO**, go to **2**

1. **Has the trial been assessed and approved to proceed by the US FDA or an equivalent regulatory authority?**

If **YES**: Please provide with your ethics application evidence of review and approval to proceed e.g. FDA IND number, evidence of approval to proceed and version and date of approved protocol.

If **NO**: Independent expert review of pre-clinical data must be completed before a submission can be made to the Peter MacCallum Cancer Centre Ethics Committee. **Contact** **ethics@petermac.org** regarding process for expert review of pre-clinical data.