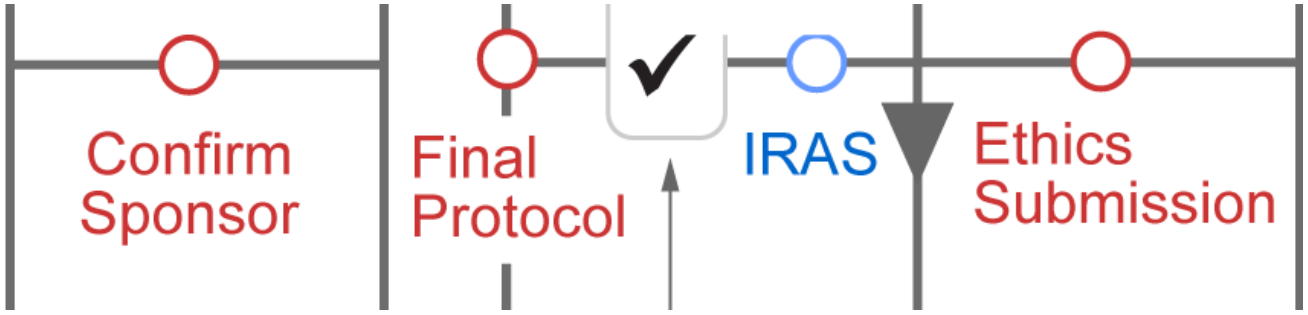
Routemap

Final Protocol



Trial Planning Phase

The Final Protocol station follows the Contracts & Agreements station and precedes the CI Checklist Before Seeking Approval and the IRAS station. This process occurs after the parallel processes of Funding Secured, Trial Master File, Trial Registration, Confirm Sponsor, Feasibility & Investigator Selection and Contracts & Agreements. The Final Protocol is a legal requirement which is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Before seeking approvals to start a trial, the protocol must be finalised, as this constitutes part of the application. Please refer to the Protocol Development station for details of protocol content.

The final protocol should be signed off by the Chief Investigator as a minimum, but usually other signatures may be required such as those from the sponsor and trial statistician. The sponsor should specify (usually in their policies/procedures) which signatures are required and the Chief Investigator should be aware of their local requirements.

In multi-site trials, it is good practice to ensure the Principal Investigator signs a protocol signature page to confirm receipt and also their agreement to work to the current version of the protocol.

In addition the Funder should be informed of any changes to a protocol and their agreement to these obtained.

Further reading:

- Gamble et al. (2017) recommend a minimum set of items that should be addressed and included in Statistical Analysis Plans for clinical trials.