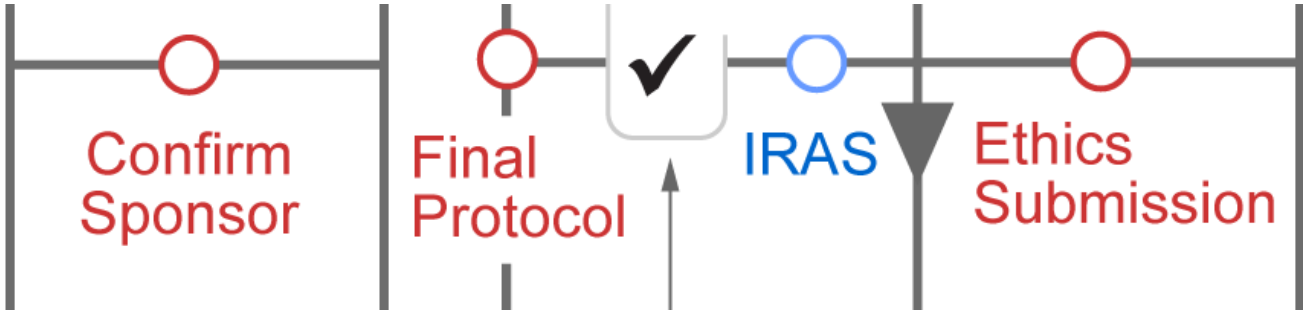
Final Protocol



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.

Final Protocol

Before seeking approvals to start a trial, the protocol must be finalised as it forms part of the application. An updated protocol template that aligns with the amended Clinical Trial Regulations is available for Clinical Trials of Investigational Medicinal Products (CTIMPs).

The Chief Investigator should sign off on the final protocol. Signatures from the sponsor and trial statistician may also be required, and the sponsor’s policies or procedures should specify which signatures are required. The Chief Investigator should ensure these local requirements are met.

In multi-centre trials, it is good practice for each Principal Investigator to sign a protocol signature page (or equivalent) to acknowledge receipt of the current version and confirm their agreement to conduct the trial in accordance with it.

In addition to oversight bodies, any changes to the protocol should be communicated to the funder and their approval obtained before implementation.

Further Reading

- Health Research Authority: Protocol guidance and template for use in a Clinical Trial of an Investigational Medicinal Product (CTIMP).
- Gamble et al. (2017) recommend a minimum set of items that should be addressed and included in Statistical Analysis Plans for clinical trials.
- SPIRIT 2025 Statement and Checklist: Defining standard protocol items for clinical trials.
- ICH E8 (R1): (.PDF) General Considerations for Trials (.PDF)