



How to submit a Protocol

Investigators have responsibilities to provide complete and accurate information for reviewers to make informed decisions on the requirements for IRB review/approval.

Below is the required set up of a submission packet of a protocol to CPDH's IRB. The actual protocol and appendices should be in one document with numbered pages; appendices should be appropriately titled and clearly labeled. Only final versions (no drafts) are accepted and must not include documents in track changes format.

Submission packet should follow this order:

- 1) Cover Letter
- 2) CDPH IRB Application
- 3) Protocol as one document:
 - a. Title page with name of study, date, version number, PI and Co-Investigator name(s), and CDPH Sponsor(s) name.
 - b. Table of contents
 - c. List of abbreviations
 - d. Body of the main protocol
 - e. Clearly labeled appendices (consent forms, data collection forms, questionnaires etc)
- 4) Other supporting documents, such as approvals by other IRBs