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