Amending an IRB application

Follow the steps outline below when amending an IRB application and supporting documents (e.g., Protocol, Recruitment materials, and Consent forms). Following this guidance will help in the review process as well as chronologically organize changes. Samples have been provided to illustrate proper formatting.

Amending the Application:
1. **Do not delete or change previously approved text within the application.**
2. Starting below previously approved text, create a header with the amendment number (e.g., Ame12345”). Describe only what has changed, it is not necessary to repeat previously approved information. **This format should be followed in each amended section.**
3. Provide a brief outline of the amendment in 1.8 Project Summary.

Amending Supporting Documents:
1. When amending a **Stand-Alone Protocol**, go to the END of the document, create a header with the amendment number (e.g., “Ame12345”), and speak to only what has changed with the amendment. **Do not delete or change previously approved text.**
2. Revisions to consents and recruitment materials should be done within the body of the document.
3. Title all revised documents with the Amendment #. Use a consistent and descriptive naming convention.
4. Provide Track-Change versions of all amended documents in section 4.4. Upload clean versions to the appropriate section(s).