



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.

*****Amendment 1 (Ame001[REDACTED]) - June/July 2022

- 1) Consent: a) add waiver of consent for signature in case there are technical issues with electronic signing in redcap for providers (only for providers who experience a technical glitch in signing), b) add email privacy questions for provider consent, c) edit text of provider consent to convey incentives for provider participants (gift baskets given to all providers at end of study) and weekly fidelity/session summary survey for providers, and d) add emergency contact information for clients.
- 2) Protocol: a) add section on assessment timing details T2-T4 providers and clients, b) edit incentives for provider participants (gift baskets given to all providers at end of study), c) add fidelity, and d) add provider weekly session summary and fidelity self-rating survey.
- 3) Screener: add 'capacity' to a list of exclusions in question 12 that research staff complete for clients
- 4) assessments: a) add gender question for providers, b) add N/A categories for providers not delivering the treatment, c) add question for clients T1-T4 regarding medication information, d) adding provider weekly session surveys, and e) adding fidelity assessments that research staff complete.
- 5) [REDACTED]
- 6) Recruitment: add recruitment flyer email

Amending Stand-Alone Protocol: (*NEW*)

1. Create a **clean** and **Track Change** version with the amendment number in the document title and upload both to 5.1.1.
2. Revise the relevant sections within the body of the protocol.
3. Follow this [guidance](#) for stacking documents.

Amending Supporting Documents:

4. Revisions to consents and recruitment materials should be done within the body of the document.
5. Title revised documents with the Amendment #. Use a consistent and descriptive naming convention.
6. Provide Track-Change versions of amended documents in section 44. Upload clean versions to the appropriate section(s).

Filename	Version
AME00009880_PPDS T1 Blood briefing talking points.docx History	0.01
AME00009880_PPDS T1 Survey briefing talking points.docx History	0.01
AME00009880_PPDS T2 Survey briefing talking points.docx History	0.01
AME00009880_PPDS Video Script.docx History	0.01
AME00009880_PPDS T3 01_Email Prenotification 20130127.docx History	0.01
AME00009880_PPDS T3 02_Email Invitation 20130127.docx History	0.01
AME00009880_PPDS T3 03_Letter follow-up to Email invitation 20130127.docx History	0.01
AME00009880_PPDS T3 04_SMS follow-up to Email invitation 20130127.docx History	0.01
AME00009880_PPDS T3 05_Email Reminders 20130127.docx History	0.01
HUM00009880_ABOUT the Study 3-10-11.docx History	0.01
HUM00009880_ABOUT US-intro 03-10-11.docx History	0.01
HUM00009880_ArmyStarrs_Update20110310_HiRes.pdf History	0.01
HUM00009880_Biographies 03-10-11.docx History	0.01
HUM00009880_FB Q&A for installationsUPDATEI20110310.docx History	0.01

AME00009880_AAS Consent Form TRACK CHANGES 20110205.doc	0.01
AME00009880_AAS Consent Form TRACK CHANGES 20110309.doc	0.01
AME00009880_AAS Consent Form ZB TRACK 20110316.doc	0.01
AME00009880_AAS Consent Presentation TRACK CHANGES 20110309 .doc	0.01
AME00009880_AAS Consent Presentation TRACK CHANGES.doc	0.01
AME00009880_AAS Resource card_02042011.doc	0.01
AME00009880_AAS SIB Instructions.doc	0.01
AME00022041_AAS_CAI_Feb 7 TRACK CHANGES.docx	0.01