## HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB UNIVERSITY OF MICHIGAN

# 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. <u>Do not delete or change previously approved</u> text within the application.
- 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.

segrant proposal lists two main aims (a leasionity that and main that) and one sub-aim. This application is for just one main aim: the main trial. The feasibility trial is not being conducted and the sub-aim may be conducted in the future but this would be added as an amendment at a later time. "End Ame00048705"

## \*\*\*Begin Ame00050595\*\*\*

This amendment includes the following updates: minor changes to the online assessments and survey endings (to have consistency across the three surveys, I decided to add questions about past 6-weeks to the baseline and change past 12 weeks to past 6 weeks in the 12-week follow-up). To the intervention messages, I also made minor changes to the week 1 messages to account for the nuances in opting-in for conditions E2, E3, F2, F3, G2, G3, H2, and H3. I also made very minor changes to the survey recruitment/reminder emails. \*\*End Ame00050595\*\*\*

3. Provide a brief outline of the amendment in 1.8 Project Summary.

## **Amending Supporting Documents:**

- When amending a Stand-Alone Protocol, go to the <u>END</u> of the document, create a header with the amendment number (e.g., "Ame12345"), and speak to only what has changed with the amendment. <u>Do</u> <u>not delete or change previously approved text.</u>
- **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 44. Upload clean versions to the appropriate section(s).

aine		Version
AME00029	880 PPDS T1 Blood briefing talking points.docx   History	0.01
AME00029	880 PPDS T1 Survey briefing talking points.docx   History	0.01
AME00031	009 PPDS T2 Survey briefing talking points.docx   History	0.01
AME00032	537 PTDS Video Script.docx   History	0.01
AME00035	126 PPDS T3 01_Email Prenotification 20130127.docx   History	0.01
AME00035	126 PPDS T3 02_Email Invitation 20130127.docx   History	0.01
AME00035	126 PPDS T3 03_Letter follow-up to Email invitation 20130127.docx   History	0.01
AME00035	126 PPDS T3 04_SMS follow-up to Email invitation 20130127.docx   History	0.01
AME00035	26 PPDS T3 05_Email Reminders 20130127.docx   History	0.01
HUM0005	18 About the Study 3-10-11.docx   History	0.01
HUM0005	18 ABOUT US-intro 03-10-1.docx   History	0.01
HUM0005	18 Ar rrs_Update20110310_HiRes.pdf   History	0.01
HUM0005	18 Biographies 03-10-11.docx   History	0.01
UM0005	18 FB Q&A for installationsUPDATEI20110310.docx   History	0.01
		0.01

#### allow, up.research\_design.REVISED.CLEAN.20161108.egiftcard.add\_text.paper\_int.2017-0613.ame77058desktop\_added.2018-0131-1.4 Developer ACROBAT Q Tell me what you want to do...

ABBCCDC ABBCCDC ABBCCDC ABBCCD ABBCCD ABBCCD ABBCCDC ABBCCDCCD ABBCCDC ABBCCDC ABBCCDC ABBCCDC

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Content or nacebook posts will be dove of names or test for communications and set in nature threats of weapon carrying, weapon use, general threats of violence, and aggressive words, using the same general coding approach noted for coding tweets. This is an innovative pilot measure of violence that we will refine in these studies. We will examine how it relates to other measures of violence, and whether it has independent relations to our measures of exposure to violence. Thus, we will be able to link ratings of participants' Facebook posts with data collected from their parent/close friend, and the participant's own self-report data and archival data about them to gain a multi-source picture of their contextual environment and their attitudes and behaviors.

## AME 67119

Procedures. We expect that most of the participants will be interviewed in their homes or in an agreed upon quiet public location (e.g., public library). However, for participants who no longer live in the Flint area, we want to conduct the interview by phone, in the same manner that we are conducting phone interviews for parent/close friends. That is, oral consent will be gained, and the interview will proceed with the interviewer entering the participant's responses into the tablet. At the end of the interview, the participant will be gained as \$50 gift card for their time.

### AME67716

Procedures. At the end of the phone interview, participants will be given payment options. They can decide to receive a check in the mail or an Amazon gift card via email.

### AME67851

Procedures. At the end of the phone interview, participants are given payment options. They can decide to receive a check in the mail or an Amazon gift card via email. Because many of our participants do not use email, we would like to add the option of having the link to the <u>egift</u> card delivered by text message.

### AME7076

Procedures. In the rare event that a tablet malfunctions and the survey cannot be conducted on the tablet offline, the interviewer will try to have a second tablet on hand, but if that is not possible, the interviewer might conduct the survey using a paper copy.

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AME00022041 AAS Consent Form TRACK CHANGES 20110205.doc	0.01
AME00022041 AAS Consent Form TRACK CHANGES 20110309.doc	0.01
AME00022041 AAS Consent Form ZB TRACK 20110316.doc	0.01
AME00022041 AAS Consent Presentation TRACK CHANGES 20110309 .doc	0.01
AME00022041 AAS Consent Presentation TRACK CHANGES.doc	0.01
AME00022041 AAS Resource card_02042011.doc	0.01
AME00022041 AAS SIB Instructions.doc	0.01
AME00022041 AAS CAL Feb 7 TRACK CHANGES.docx	0.01