Northwestern | RESEARCH

Northwestern University
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APPROVAL OF MODIFICATION AND CONTINUING REVIEW

DATE: March 25, 2024

TO: Dr. Bruce Lambert
FROM: Office of the IRB

DETERMINATION DATE: 3/25/2024
APPROVAL DATE: 3/25/2024
EXPIRATION DATE: 3/24/2025

The Northwestern University IRB has reviewed and approved the submission described below:

Type of Submission:	Modification and Continuing Review
Review Level:	Expedited
Expedited Category:	- (7) Behavioral research/social science methods
Title of Study:	Comparative Effectiveness of Various Methods of Text Enhancement in Simulated Drug Selection Tasks
Principal Investigator:	Bruce Lambert
IRB ID:	STU00218106-MODCR0001
Funding Source:	Name: Food and Drug Administration, Grant Office ID: SP0075169, Funding Source ID: 75F40122C00191
IND, IDE, or HDE:	None
Documents Reviewed:	• Drug Name Confusion Recruitment Email.docx, Category: Recruitment Materials; • Aim 1 Verbal Consent Form 2023_02_15 v 0.02.pdf, Category: Consent Form; • Drug Name Confusion Recruitment Flyer (Clinicians and Trainees).doc, Category: Recruitment Materials; • Familiarity Questionnaire.doc, Category: Questionnaire/Survey; • Drug Name Confusion Phone Script 2023_02_27 v.2.doc, Category: Recruitment Materials; • Demographic Questionnaire For Main Experiment.doc, Category: Questionnaire/Survey; • Drug Name Confusion Experiment Debriefing.docx, Category: Debriefing Script; • Drug Name Text Enhancement protocol 2023_04_13 v.3.pdf, Category: IRB Protocol; • Supporting Document for STU00218106 (2024_03_08).docx, Category: Continuing Review Supporting Document;
Special Determination(s):	Waiver of documentation of consent;

Unaffiliated External Site(s) that rely on NU IRB:	None
Clinical Trial:	No

Description of the modification:

No modifications requested except to remove Kerstin Kalke who was an RA who has moved on to another appointment.

If your study was deemed a clinical trial upon IRB approval, you should have already registered your study in the ClinicalTrials.gov PRS within 21 days of enrollment of the first participant. If you have not yet registered your study, please contact the NU PRS Administrator at clinicaltrials.gov@northwestern.edu. If you have registered, please note that clinical trial registration information submitted to ClinicalTrials.gov must be updated not less than once every 12 months. Please visit the clinical trials page on the IRB website for more information.

In conducting this study, you are required to follow the requirements listed in the Northwestern University (NU) Investigator Manual (HRP-103), which can be found by navigating to the policy section of the IRB website. Additionally, as Principal Investigator (PI) of this research study, you are expected to adhere to the investigator responsibilities outlined in the "What are my obligations as Investigator in order to conduct Human Research" section of the Investigator Manual (HRP-103).

CR: If you are unable to complete the study within the approval period, you will need to submit a continuing review to renew the study. The continuing review must be submitted no more than 60 days prior to the expiration date.

All Non-Exempt Human Research, including studies without a continuing review, are subject to routine IRB post-approval monitoring as outlined in the "What are my obligations as Investigator in order to conduct Human Research" section of the Investigator Manual (HRP-103) and the "Reporting Concerns" section of the Human Research Protection Program Compliance (HRPP).

NU IRB approval does not constitute or guarantee institutional approval and/or support. Investigators and study team members must comply with all applicable federal, state, and local laws, as well as NU Policies and Procedures, which may include obtaining approval for your research activities from other individuals or entities.

For IRB-related questions, please consult the NU IRB website at http://irb.northwestern.edu. For general research questions, please consult the NU Office for Research website at www.research.northwestern.edu.