Intramural Research Program
Our Research Changes Lives

LETTER OF CONTINUING REVIEW APPROVAL

DATE: December 11, 2019

TO: Susan J Persky
NHGRI - HG - SB

FROM: Nicole Drbohlav Grant
National Institutes of Health (NIH)
Institutional Review Board (IRB)

RE: Continuing Review:
iRIS Reference #: 538785
Patient Provider Communication and Interaction in a Virtual Clinical Setting

IRB Protocol #: 08HG0122

IRB Approval Date: 12/11/2019
Expiration Date: 12/28/2020
12 Months
Risk Level: Not Greater than Minimal Risk under 45 CFR 46
Review Level: Expedited
Subjects Approved: 558

List of documents approved with submission: Submission Components Approved		
Document Type	Version	Date Approved
Submission-Continuing Review Form	Version 12.1	12/11/2019
Consent Form-Study 2	Version 1.0	12/11/2019
Document-08HG0122 Protocol CLEAN 04JUL2019	Version 1.1	12/11/2019

The Continuing Review for your above-referenced protocol was reviewed and **Approved** in accordance with Federal regulations 45 CFR 46 under the National Institutes of Health's Federalwide Assurance (FWA00005897).

The submission will now be forwarded to the NIH Clinical Center (CC) Office of Protocol Services (OPS) for administrative processing. You will receive your final approval documents once the CC OPS has completed their processing.

Regulatory Determinations:

Expedited Review Category:
Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Documentation of Informed Consent:
Written consent in accordance with 45 CFR 46.117

Short form-oral presentation approved under 45 CFR 46.117 (b) (2)

Federal regulations and NIH policy require that you report promptly any unanticipated problems involving risks to subjects or others, or serious harm involving subjects, to the IRB. In addition, substantive changes in research activities, during the period for which IRB approval has been given, may not be initiated by you without prior review and approval by the IRB, except where necessary to eliminate apparent immediate hazard to subjects.

If you have any questions please contact the IRB Administrative Office (phone: 301-402-3713 / email: IRB@od.nih.gov).