INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

Office of Research Compliance

NOTICE OF EXPEDITED APPROVAL - RENEWAL WITH AMENDMENT

DATE:	March 30, 2020
TO:	Richard Holden, Principal Investigator SCHOOL OF MEDICINE
FROM:	Turik, Michael A Chair - IRB-04
RE:	Protocol #: 1606267154R002 Protocol Type: Expedited Protocol Title: I-CARE Funding Source: 0051391200538428

The Indiana University Institutional Review Board (IRB) IRB 00000219 | IRB-04 recently reviewed and approved the above-reference protocol. Approval of this protocol is based on your agreement to abide by the policies and procedures of the Indiana University Human Research Protection Program (HRPP) and does not replace any other approvals that may be required. Relevant HRPP policies and procedures governing Human Subject Research can be found at: https://research.iu.edu/compliance/human-subjects/guidance/index.html.

Submission and Review Information:

Type of Submission:	Renewal with Amendment
Level of Review:	Expedited
Expedited Category(ies), if applicable:	Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
Approval Date of Submission:	March 30, 2020
Expiration Date:	
Authorized IRB Signature	Kelly M. Anderson Kelly Anderson

Regulatory Determinations:

- Study continues to meet the criteria for approval defined by the HRPP Policy on IRB Review Process and 45 CFR 46.111
- Research complies with and is subject to 45 CFR 46 effective January 21, 2019 (i.e. Revised Common Rule or 2018 Requirements).
- Previously-approved subjects are not required to be reconsented with additional elements of consent per 2018 Requirements.
- The PHI to be used or disclosed is determined to be necessary

- The explanation of how this research involves no more than minimal risk of loss of privacy to the subject is sufficient
- There exists an adequate plan to protect the identifiers from improper use and disclosure
- There exists an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research
- There exist adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule
- The explanation of how this research could not be practicably conducted without waiver of authorization is adequate
- The explanation of how this research could not be practicably conducted without access to and use of the individually identifiable health information is appropriate
- Alteration of authorization under 45 CFR 164.512(i)
- PHI to be used or disclosed:
    - o For participation: Names, date of birth, age, address, phone number, MRN.

Documents Approved with this Submission (for Amendments and Renewals, documents appearing in bold were either added or replaced with the submission):

Attachment Type - Document Version #
Data Collection Instrument - SILS - this is a single item literacy assessment
Data Collection Instrument - SUS - 10 item assessment focused on system usability
Data Collection Instrument - Acceptance BI - assessment focus on determining how frequent the subject would like to use the system
Data Collection Instrument - Demographics
Data Collection Instrument - EMR extraction- data collection from subjects EMR
Data Collection Instrument - iCare Neuropsychiatric Inventory+Caregiver Distress
HIPAA Authorization Form (Non-VA) - updated HIPPA 10-2-2019
Informed Consent Statement - ICS
Informed Consent Statement - final version-stamped
Protocol - iCare Research Protocol
Recruitment Materials - iCare Letter to Physicians
Recruitment Materials - Telephone contact script

NOTE: If you submitted and/or are required to provide subjects with an informed consent document, please ensure you are using the most recent version of the document to consent subjects.

The following key personnel are approved to participate in the above titled research activities:

Investigator Name	**Role**	**Training**
Richard Holden	Principal Investigator	Yes
Malaz Boustani	Key Personnel	Yes
Daniel Clark	Key Personnel	Yes
Devika Davda	Key Personnel	Yes
Nicole Fowler	Key Personnel	Yes
Addison Harrington	Key Personnel	Yes
Alexxus Knight	Key Personnel	Yes
Patrick Monahan	Key Personnel	Yes
Doris Muriathiri	Key Personnel	Yes

Organizations:

Organization
REGENSTRIEF INSTITUTE, INC.
HEALTH AND HOSPITAL CORPORATION OF MARION COUNTY
IU HEALTH
ESKENAZI HEALTH
Indiana University

You should retain a copy of this letter and all associated approved study documents for your records. Please refer to the assigned study number and exact study title in future correspondence with our office. Additional information is available on our website at https://research.iu.edu/compliance/human-subjects/guidance/index.html.

If you have any questions or require further information, please contact the HSO via email at irb@iu.edu or via phone at (317)274-8289.