

**JHSPH Institutional Review Board Office**

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**APPROVAL/DETERMINATION MEMO**

**Continuing Review**

Date: September 30, 2021

To: Hadi Hadji Karim Kharrazi, PhD  
Department of Health Policy and Management

From: Katherine C. Smith, PhD  
Chair, IRB- X

Study Title: Addressing Suicide Research Gaps: Understanding Mortality Outcomes in the Mid-Atlantic Region

IRB No.: 9022/CR699

<input type="checkbox"/> Approved <input type="checkbox"/> Approved, minor change (single reviewer) <input type="checkbox"/> Approved Expedited Cat: <input checked="" type="checkbox"/> Determined to be Exempt Cat: (4)	Approval/Determination Date: September 16, 2021 Approval Lapse Date: September 15, 2024
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As Principal Investigator for this IRB approved study, you are responsible for conducting the study in accordance with the ethical principles of the Belmont Report, in compliance with all relevant laws and regulations, and in accordance with JHU institutional policy.

<b>DHHS</b> <input checked="" type="checkbox"/> 45 CFR 46 <input checked="" type="checkbox"/> CR <input type="checkbox"/> Revised CR <b>FDA</b> <input type="checkbox"/> 21 CFR 50, 56 <input type="checkbox"/> IND, 21 CFR 312 <input type="checkbox"/> IDE, 21 CFR 812 <input type="checkbox"/> IND/IDE held by JHSPH PI <input type="checkbox"/> Dept. of Defense Funding <input type="checkbox"/> Min. Risk	<b>*Consent/Parental Permission Required From:</b> <input type="checkbox"/> Adult Participant <input type="checkbox"/> LAR <input type="checkbox"/> One Parent <input type="checkbox"/> Two Parents 46.406, 50.53 <input type="checkbox"/> Legal Guardian of Children in Foster Care <input type="checkbox"/> Minor Consent as Adult	<b>*Adult Consent:</b> <input type="checkbox"/> Written Consent <input type="checkbox"/> Waiver of Signature <input type="checkbox"/> Exempt (Electronic) <input type="checkbox"/> Alteration of Consent; meets 46.116 (f)(3) criteria <input type="checkbox"/> Waiver of Informed Consent; meets 46.116 (f)(3) criteria	<b>*Parental Permission:</b> <input type="checkbox"/> Written Permission <input type="checkbox"/> Waiver of Signature <input type="checkbox"/> Exempt (Electronic) <input type="checkbox"/> Alteration of Permission; meets 46.116 (f)(3) criteria <input type="checkbox"/> Waiver of Permission; <input type="checkbox"/> Meets 46.116 (f)(3) <input type="checkbox"/> 46.408, with Substitute Mechanism provided
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<input type="checkbox"/> Greater than min. risk <input type="checkbox"/> GWAS <input type="checkbox"/> Reliance Agreement <input type="checkbox"/> Clinical Trial/GCP <b>*Study Site(s):</b> <input type="checkbox"/> U.S. <input type="checkbox"/> International <b>*List Country(ies):</b>	<b>*Vulnerable Populations:</b> <input type="checkbox"/> Children <input type="checkbox"/> Foster Care Children <b>DHHS</b> <b>FDA</b> <input type="checkbox"/> 46.404 <input type="checkbox"/> 50.51 <input type="checkbox"/> 46.405 <input type="checkbox"/> 50.52 <input type="checkbox"/> 46.406 <input type="checkbox"/> 50.53 <input type="checkbox"/> Preg. Women/Fetuses 46.204 <input type="checkbox"/> Neonates <input type="checkbox"/> Prisoners	<b>*Assent:</b> <input type="checkbox"/> Written (signed) <input type="checkbox"/> Oral <input type="checkbox"/> Statement in Parent Permission Form <input type="checkbox"/> Electronic <input type="checkbox"/> Waived for all children <input type="checkbox"/> Waived for children <b>*HIPAA:</b> <input type="checkbox"/> JHM <input type="checkbox"/> Non-JHM <input type="checkbox"/> Authorization <input type="checkbox"/> Prep. To Research <input type="checkbox"/> HIPAA Alteration/Waiver <input type="checkbox"/> JHM Data Tracking <input type="checkbox"/> Limited Data Set <input type="checkbox"/> DUA	<b>*Sample Size:</b> (screened plus enrolled)  <b>*Final Enrollment:</b>  <b>*Secondary Data Analysis:</b> (specimens/participants)
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As principal investigator of IRB approved research, you are responsible for meeting the following requirements of approval:

- 1) Informing the co-investigators listed on the application of the status of the research.
- 2) Submitting an Amendment Application or Administrative Amendment for any changes in research. These changes in research are required to be reviewed and approved prior to the activation of the changes, unless you are correcting or clarifying language in approved instruments.
- 3) Reporting Unanticipated problems involving risk of harm to participants or others that are related to the study procedures to the JHSPH IRB within 10 days of the time that the PI learns of such problems. Submit a Problem Event Report Form must be submitted to the IRB immediately.
- 4) Using only the most recently approved JHSPH IRB approved consent forms, with the JHSPH stamp or logo, unless otherwise approved by the IRB. All consent forms signed by subjects enrolled in the study should be stored securely, in paper or electronic form, until 3 years following study completion unless otherwise approved by the IRB.
- 5) Submitting in a timely fashion Continuing Review Applications or Progress Reports. The Approval Lapse Date above marks the end of this approval; no study activity may take place after that date without new IRB approval. Submit your report to the IRB Office no later than six weeks prior to the approval lapse date to allow time for IRB review to be completed prior to that date.

6) If your study is an NIH funded clinical trial, e.g., “A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes”, it must be registered on [clinicaltrials.gov](https://clinicaltrials.gov), and one IRB approved consent form used in the study must be posted on a publicly available Federal website.

7) If your research involves international travel, please don't forget to register with the International Travel Registry <https://travelregistry.johnshopkins.edu/Travel> so that the school may locate you in the event of an emergency.

KS/sro