GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

DATE: February 26, 2021

TO: Dianne Green-Smith
FROM: GVSU Institutional Review Board (IRB)
STUDY TITLE: Professionals' perceptions on school-based interventions for students with mental health problems s in Ghana.
REFERENCE #: 21-186-H
SUBMISSION TYPE: IRB Initial Submission

ACTION: Exempt Determination
EFFECTIVE DATE: February 26, 2021
REVIEW TYPE: Exempt Review

Thank you for your submission of materials for your research study. It has been determined that this project is human subjects research according to current federal regulations and MEETS eligibility for exempt determination under Exempt Category 2, GVSU IRB Policy 911, "Exemption determinations and research ethics standards," and 45 CFR 46.104 when applicable. You may now proceed with your research.

The following personnel are permitted to work on this protocol:

- Dianne Green-Smith - Principal Investigator
- Marigold Cobbina - Co-Investigator, Student

Exempt protocols do not require formal approval, renewal or closure by the IRB. However, any revision to exempt research that alters the risk/benefit ratio or affects eligibility for exempt review must be reviewed and acknowledged by the IRB prior to implementing the change. All personnel additions must also be reviewed and permitted by the Office of Research Compliance and Integrity before the individual can begin work on the protocol. Requests for revisions and personnel additions must be submitted using the *IRB Amendment Request Form*.

Any research-related problem or event resulting in a fatality or hospitalization requires immediate notification to the Office of Research Compliance and Integrity (rci@gvsu.edu or 616-331-3197), the IRB chair, Dr. Kevin Lehnert at (616) 331-7471 **and** the Research Integrity Officer Jeffrey Potteiger at 616-331-7207. (See *IRB policy 1020, Reportable events: protocol deviations, unanticipated problems and adverse events*.)

Protocol deviations that do not impact participant safety, confidentiality, information security or privacy only require reporting to the IRB if they affect ten or more participants, or 10% of the total sample population, whichever is smaller, within a one-year period. Use the *IRB Reportable Event form* in IRBManager to report this information. (See *IRB policy 1030, Research non-compliance.* Refer to *IRB policy 1020, Reportable events: protocol deviations, unanticipated problems and adverse events* for examples of reportable protocol deviations.)

Further, it is the researcher's responsibility to continue to monitor this GVSU website for additional corona virus guidance provided by GVSU as well as all state, federal, and CDC guidelines for minimizing the risk of infection. In the event that new data regarding transmission minimization or guidelines for risk mitigation emerge, the researcher should submit a change in protocol to remain in compliance with new recommendations for safety to the participants and the researchers.

While not required, it is highly recommended that this research by closed when it is completed by submitting the *IRB Closure Form.* Exempt research studies are eligible for post-approval compliance reviews and will remain eligible for these reviews until the research has been closed.

If you have any questions, please contact the Office of Research Compliance and Integrity at 616-331-3197 or rci@gvsu.edu. Please include your study title and protocol number in all correspondence with our office.