MEMORANDUM

DATE: October 14, 2018

TO: Gerard Francis Lawson, Jyotsana Sharma

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: Socio-Cultural Contexts in Trauma Recovery and Posttraumatic Growth

IRB NUMBER: 18-819

The Virginia Tech Institution Review Board (IRB), acknowledges the Amendment request for the above-mentioned research protocol.

This acknowledgement recognizes the item(s) identified in the Special Instructions section.

NOTE: Please ensure that required Amendments are submitted to WIRB for review and approval. WIRB guidance is provided on page 49 of the Guide for Researchers. The section is titled Changes to Research / Additional Document Submissions. The document is located at: http://wirb.com/Documents/Guide%20for%20Researchers.pdf#page=2
IRB SPECIAL INSTRUCTIONS:
This Amendment Acknowledgement includes the WIRB certificate of action, WIRB smart form, and WIRB-approved consent form and recruitment materials.

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<th>Sponsor</th>
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* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.
This is to certify that the information contained herein is true and correct as reflected in the records of this IRB. WE CERTIFY THAT THIS IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

**Investigator Name:** Gerard Lawson, PhD  
**Board Action Date:** 10/05/2018

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<tr>
<th>Investigator Address:</th>
<th>Approval Expires:</th>
<th>Continuing Review Frequency:</th>
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| 1750 Kraft Dr., Suite 2000  
Blacksburg, VA 24060, United States | 10/05/2019 | Annually |

**Investigator Address:**  
1750 Kraft Dr., Suite 2000  
Blacksburg, VA 24060, United States

**Approval Expires:** 10/05/2019  
**Continuing Review Frequency:** Annually

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<tr>
<th>Sponsor:</th>
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<tr>
<td>Virginia Tech</td>
<td>None</td>
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**Study Number:** 1247799  
**IRB Tracking Number:** 20182554

**Work Order Number:** 1-1117893-1  
**Panel:** 1

**Protocol Title:** Socio-Cultural Contexts in Trauma Recovery and Posttraumatic Growth

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**THE FOLLOWING ITEMS ARE APPROVED:**

- Investigator Advertisement - Are You a Survivor Share #22851885.0 - As Submitted
- Follow-up Interview Protocol #22851888.0 - As Submitted
- Interview Protocol #22851887.0 - As Submitted
- Participant Screening Questionnaire #22851886.0 - As Submitted
- Protocol Consent Form [IN0]
- Investigator Advertisement - Recruiting through Professionals For Professionals #22851889.0 - As Submitted
- Screening Script #22892182.0 - As Submitted

**Please note the following information:**

The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

**THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:**

Virginia Tech, 1750 Kraft Dr., Suite 2000, Blacksburg, Virginia 24060

**ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:**

As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
  - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB’s oversight) when:
  - The protocol is permanently closed to enrollment
  - All subjects have completed all protocol related interventions and interactions
  - For research subject to federal oversight other than FDA:
    - No additional identifiable private information about the subjects is being obtained
    - Analysis of private identifiable information is completed
• If research approval expires, stop all research activities and immediately contact the IRB.
• Promptly report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
• Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
• Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
• When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
• Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:
• Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
• Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
• Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
• Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement.

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from this IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

DISTRIBUTION OF COPIES:
Contact, Company
Jennifer Farmer, Virginia Tech
Jyotsana Sharma, Virginia Tech
Gerard Lawson, PhD, Virginia Tech
MEMORANDUM

DATE: June 2, 2019

TO: Gerard Francis Lawson, Jyotsana Sharma

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: Socio-Cultural Contexts in Trauma Recovery and Posttraumatic Growth

IRB NUMBER: 18-819

Effective June 2, 2019, the Virginia Tech Institution Review Board (IRB) approved the Amendment request for the above-mentioned research protocol. This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:
https://secure.research.vt.edu/external/irb/responsibilities.htm
(Please review responsibilities before beginning your research.)

PROTOCOL INFORMATION:

Approved As: Expedited, under 45 CFR 46.110 category(ies) 6,7
Protocol Approval Date: October 5, 2018
Protocol Expiration Date: October 5, 2019
Continuing Review Due Date*: September 21, 2019

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

ASSOCIATED FUNDING:

The table on the following page indicates whether grant proposals are related to this protocol, and which of the listed proposals, if any, have been compared to this protocol, if required.
**SPECIAL INSTRUCTIONS:**

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This amendment, submitted by the HRPP office, acknowledges the transfer of IRB oversight from WIRB back to the Virginia Tech HRPP/IRB office for this protocol. Please ensure that all amendments, continuing reviews, adverse events, progress report, or study closure are submitted to Virginia Tech from this point forward.

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