

March 16, 2017

Paul Estabrooks, PhD
COPH Hlth Pr, Soc & Behv Health
UNMC - 4365

IRB # 161-17-EX

TITLE OF PROPOSAL: Feature-based Designs to Increase Reach of Effective Weight-Loss Programs

The Office of Regulatory Affairs (ORA) has reviewed your application for *Exempt Educational, Behavioral, and Social Science Research* on the above-titled research project. According to the information provided, this project is exempt under 45 CFR 46:101b, category 2. You are therefore authorized to begin the research.

It is understood this project will be conducted in full accordance with all applicable HRRP Policies. It is also understood that the ORA will be immediately notified of any proposed changes for your research project.

Please be advised that this research has a maximum **approval period of 5 years** from the original date of approval and release.


If the research is completed prior to 5 years, please notify the Office of Regulatory Affairs at irbora@unmc.edu. If this study continues beyond the five year approval period, the project must be resubmitted in order to maintain an active approval status.

Sincerely,

Signed on: 2017-03-16 15:26:00.000

Gail Kotulak, BS, CIP
IRB Administrator III
Office of Regulatory Affairs

MEMORANDUM

DATE: March 7, 2017 

TO: Wen You, Linda L Staley, Paul Estabrooks

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

PROTOCOL TITLE: Feature-based Designs to Increase Reach of Effective Weight-Loss Programs

IRB NUMBER: 16-858

Effective March 7, 2017, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, 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: <http://www.irb.vt.edu/pages/responsibilities.htm>

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Exempt, under 45 CFR 46.110 category(ies) 2**
Protocol Approval Date: **November 3, 2016**
Protocol Expiration Date: **N/A**
Continuing Review Due Date*: **N/A**

*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.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

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

Date*	OSP Number	Sponsor	Grant Comparison Conducted?

* 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.

MEMORANDUM

DATE: November 4, 2016

TO: Wen You, Linda L Staley, Paul Estabrooks

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

PROTOCOL TITLE: Feature-based Designs to Increase Reach of Effective Weight-Loss Programs

IRB NUMBER: 16-858

Effective November 3, 2016, the Virginia Tech Institutional Review Board (IRB) Chair, David M Moore, approved the New Application 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:

<http://www.irb.vt.edu/pages/responsibilities.htm>

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Exempt, under 45 CFR 46.110 category(ies) 2**

Protocol Approval Date: **November 3, 2016**

Protocol Expiration Date: **N/A**

Continuing Review Due Date*: **N/A**

*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.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

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