DATE: December 23, 2009

MEMORANDUM

TO: France Belanger
    Lucian Zelazny
    David P. Tegarden

FROM: David M. Moore

SUBJECT: IRB Expedited Approval: "ISD Success - Interviews", IRB # 09-1038

This memo is regarding the above-mentioned protocol. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. As Chair of the Virginia Tech Institutional Review Board, I have granted approval to the study for a period of 12 months, effective December 23, 2009.

As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

3. Report promptly to the IRB of the study’s closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher’s responsibility to obtain re-approval from the IRB before the study’s expiration date.

4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

Important:
If you are conducting federally funded non-exempt research, please send the applicable OSP/grant proposal to the IRB office, once available. OSP funds may not be released until the IRB has compared and found consistent the proposal and related IRB application.

cc: File
MEMORANDUM

DATE: March 23, 2010

TO: France Belanger, Lucian Zelazny, David P. Tegarden

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires June 13, 2011)

PROTOCOL TITLE: ISD Success - Interviews

IRB NUMBER: 09-1038

As of March 23, 2010, the Virginia Tech IRB Chair, Dr. 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 promptly 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 before the commencement of your research).

PROTOCOL INFORMATION:
Approved as: Expedited, under 45 CFR 46.110 category(ies) 6,7
Protocol Approval Date: 12/23/2009
Protocol Expiration Date: 12/22/2010
Continuing Review Due Date*: 12/8/2010

*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 federally 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.
If this IRB protocol is to cover any other grant proposals, please contact the IRB office  
(irbadmin@vt.edu) immediately.

Date* | OSP Number | Sponsor | Grant Comparison Conducted? |
-------|------------|---------|-----------------------------|
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*Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

cc: File
MEMORANDUM

DATE: December 1, 2010

TO: France Belanger, Lucian Zelazny, David P. Tegarden

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires October 26, 2013)

PROTOCOL TITLE: ISD Success - Interviews

IRB NUMBER: 09-1038

Effective December 23, 2010, the Virginia Tech IRB Chair, Dr. David M. Moore, approved the continuation 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 promptly 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 before the commencement of your research).

PROTOCOL INFORMATION:
Approved as: Expedited, under 45 CFR 46.110 category(ies) 6,7
Protocol Approval Date: 12/23/2010  (protocol's initial approval date: 12/23/2009)
Protocol Expiration Date: 12/22/2011
Continuing Review Due Date*: 12/8/2011
*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 federally 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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*Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.
MEMORANDUM

DATE: November 30, 2010

TO: France Belanger, Lucian Zelazny, David P. Tegarden

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

PROTOCOL TITLE: ISD Success Survey

IRB NUMBER: 10-1014

Effective November 29, 2010, the Virginia Tech IRB PAM, Andrea Nash, approved the new protocol 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 promptly 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 before the commencement of your research).

PROTOCOL INFORMATION:
Approved as: Exempt, under 45 CFR 46.101(b) category(ies) 2
Protocol Approval Date: 11/29/2010
Protocol Expiration Date: NA
Continuing Review Due Date*: NA

*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 federally 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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*Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

cc: File
MEMORANDUM

DATE: January 18, 2011

TO: France Belanger, Lucian Zelazny, David P. Tegarden

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires October 26, 2013)

PROTOCOL TITLE: ISD Success Survey

IRB NUMBER: 10-1014

Effective January 18, 2011, the Virginia Tech IRB Administrator, Carmen T. Green, 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 promptly 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 before the commencement of your research).

PROTOCOL INFORMATION:
Approved as: Exempt, under 45 CFR 46.101(b) category(ies) 2
Protocol Approval Date: 11/29/2010
Protocol Expiration Date: NA
Continuing Review Due Date*: NA
*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 federally 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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If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.

cc: File
MEMORANDUM

DATE: March 1, 2011

TO: France Belanger, Lucian Zelazny, David P. Tegarden

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires October 26, 2013)

PROTOCOL TITLE: ISD Success Survey

IRB NUMBER: 10-1014

Effective March 1, 2011, the Virginia Tech IRB Administrator, Carmen T. Green, 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 promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

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PROTOCOL INFORMATION:
Approved as: Exempt, under 45 CFR 46.101(b) category(ies) 2
Protocol Approval Date: 11/29/2010
Protocol Expiration Date: NA
Continuing Review Due Date*: NA

*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 federally 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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