04-188

Virginia Tech
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Institutional Review Board

Dr. David M. Moore
IRB (Human Subjects)Chair
Assistant Vice Provost for Research Compliance
CVM Phase II- Duckpond Dr., Blacksburg, VA 24061-0442
Office: 540/231-4991; FAX: 540/231-6033
email: moored@vt.edu

DATE: April 8, 2004

MEMORANDUM

TO: Karen M. Hult Political Science 0130
Edie Moussa CPAP 0520

FROM: David Moore

SUBJECT: **IRB Expedited Approval:** "Control Mechanisms in a Network Organization"
IRB # 04-188

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 April 7, 2004.

cc: File
Department .Reviewer Larkin Dudley 0520

Virginia Tech
VIRGINIA POLYTECHNIC INSTITUTE
AND STATE UNIVERSITY

Institutional Review Board

Dr. David M. Moore
IRB (Human Subjects)Chair
Assistant Vice President for Research Compliance
CVM Phase II- Duckpond Dr., Blacksburg, VA 24061-0442
Office: 540/231-4991; FAX: 540/231-6033
email: moored@vt.edu

DATE: March 8, 2005

MEMORANDUM

TO: Karen M. Hult Political Science 0130
Edie Moussa CPAP 0520

FROM: David Moore

SUBJECT: **IRB Expedited Continuation**: "Control Mechanisms in a Network Organization" IRB # 05-164 ref 04-188

This memo is regarding the above referenced protocol which was previously granted expedited approval by the IRB on April 7, 2004. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. Pursuant to your request of last week, as Chair of the Virginia Tech Institutional Review Board, I have granted approval for extension of the study for a period of 12 months, effective as of April 7, 2005.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. It is your responsibility to report to the IRB any adverse reactions that can be attributed to this study.

To continue the project past the 12-month approval period, a continuing review application must be submitted (30) days prior to the anniversary of the original approval date and a summary of the project to date must be provided. Our office will send you a reminder of this (60) days prior to the anniversary date.

Virginia Tech has an approved Federal Wide Assurance (FWA00000572, exp. 7/20/07) on file with OHRP, and its IRB Registration Number is IRB00000667.

cc: File
Department Reviewer: Larkin S. Dudley

Office of Research Compliance
Institutional Review Board
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540/231-4991 Fax: 540/231-0959
E-mail: moored@vt.edu
www.irb.vt.edu
FWA00000572(expires 7/20/07)
IRB # is IRB00000667.

DATE: March 6, 2006

MEMORANDUM

TO: Karen M. Hult
Edie Moussa

Approval date: 4/7/2006
Continuing Review Due Date:3/23/2007
Expiration Date: 4/6/2007

FROM: David M. Moore

SUBJECT: **IRB Expedited Continuation 2:** "Control Mechanisms in a Network Organization" , IRB # 05-164

This memo is regarding the above referenced protocol which was previously granted expedited approval by the IRB. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. Pursuant to your request, as Chair of the Virginia Tech Institutional Review Board, I have granted approval for extension of the study for a period of 12 months, effective as of April 7, 2006.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. 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 obtained 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.

cc: File
Department Reviewer:Larkin S. Dudley

Office of Research Compliance
Institutional Review Board
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FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: March 26, 2007

MEMORANDUM

TO: Karen M. Hult
Edie Moussa

Approval date: 4/7/2007
Continuing Review Due Date:3/23/2008
Expiration Date: 4/6/2008

FROM: David M. Moore

SUBJECT: **IRB Expedited Continuation 3:** "Control Mechanisms in a Network Organization" , IRB # 05-164

This memo is regarding the above referenced protocol which was previously granted expedited approval by the IRB. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. Pursuant to your request, as Chair of the Virginia Tech Institutional Review Board, I have granted approval for extension of the study for a period of 12 months, effective as of April 7, 2007.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. 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 obtained 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.

cc: File
Department Reviewer:Larkin S. Dudley

Office of Research Compliance
Institutional Review Board
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www.irb.vt.edu
FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: March 25, 2008

MEMORANDUM

TO: Karen M. Hult
Edie Moussa

Approval date: 4/7/2008
Continuing Review Due Date:3/23/2009
Expiration Date: 4/6/2009

FROM: David M. Moore

SUBJECT: **IRB Expedited Continuation 4:** "Control Mechanisms in a Network Organization" , IRB # 05-164

This memo is regarding the above referenced protocol which was previously granted expedited approval by the IRB. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. Pursuant to your request, as Chair of the Virginia Tech Institutional Review Board, I have granted approval for extension of the study for a period of 12 months, effective as of April 7, 2008.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. 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 obtained 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.

cc: File
Department Reviewer:Laura Jensen

Office of Research Compliance
Institutional Review Board
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Blacksburg, Virginia 24061
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e-mail moored@vt.edu
www.irb.vt.edu
FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: March 25, 2009

MEMORANDUM

TO: Karen M. Hult
Edie Moussa

Approval date: 4/7/2009
Continuing Review Due Date:3/23/2010
Expiration Date: 4/6/2010

FROM: David M. Moore

SUBJECT: **IRB Expedited Continuation 5:** "Control Mechanisms in a Network Organization" , IRB # 05-164

This memo is regarding the above referenced protocol which was previously granted expedited approval by the IRB. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. Pursuant to your request, as Chair of the Virginia Tech Institutional Review Board, I have granted approval for extension of the study for a period of 12 months, effective as of April 7, 2009.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. 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.

cc: File
Department Reviewer:Laura Jensen

Office of Research Compliance
Institutional Review Board
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Blacksburg, Virginia 24060
540/231-4606 Fax 540/231-0959
e-mail irb@vt.edu
Website: www.irb.vt.edu

MEMORANDUM

DATE: March 25, 2010

TO: Karen M. Hult, Edie Moussa

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

PROTOCOL TITLE: Control Mechanisms in a Network Organization

IRB NUMBER: 05-164

As of April 7, 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: **4/7/2010**
Protocol Expiration Date: **4/6/2011**
Continuing Review Due Date*: **3/23/2011**
*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.

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.

cc: File
Department Reviewer:Laura Jensen

Institutional Review Board
Continuing Review Request Form

INSTRUCTIONS: Email completed form and the study's current consent form (if applicable) to irb@vt.edu (PDFs preferred). Unless the protocol was originally approved as Expedited, also email a copy of the current (i.e., incorporating all amendments) Research Protocol / Initial Review Application.

1. IRB NUMBER:

05-164

2. PROJECT TITLE:

Control Mechanisms in a Complex Network

3. PRINCIPAL INVESTIGATOR

Name:	Email address:
Karen M. Hult, Ph.D.	**khult@vt.edu**

4. PROJECT STATUS:

☐ Enrollment is open
☐ All subjects have completed research interventions and the research remains active only for long-term follow-up of subjects
☐ Remaining research activities are limited to data analysis
☐ No subjects have been enrolled
☒ Other, please explain: **The dissertation is complete. We are circulating the dissertation to the committee members today for their review, and hope to schedule a dissertation defense date on or before May 4, 2011.**

5. PROVIDE THE NUMBER AND DEMOGRAPHICS OF ENROLLED PARTICIPANTS:

Sixteen participants: public policy elites, primarily middle aged white males.

☐ Unknown
☐ Not applicable

6. HOW MANY PARTICIPANTS HAVE DISCONTINUED PARTICIPATION AND WHY?

0

☐ None
☐ Not applicable

7. BRIEFLY SUMMARIZE THE STUDY PROGRESS, PRELIMINARY FINDINGS, AND ANY RECENT LITERATURE THAT MAY BE RELEVANT TO THE RESEARCH, IF ANY:

Seven of the seven dissertation chapters are complete. The dissertation is a qualitative case study, and I do not have hypotheses to test. However, my study included six propositions that I informally tested. The results generally support three of the propositions.

☐ None

8. DESCRIBE ANY ANTICIPATED OR UNFORESEEN COMPLICATIONS OR EVENTS:

☒ None

9. DESCRIBE ANY COMPLAINTS RECEIVED AND HOW THEY WERE HANDLED:

If the project expires prior to receipt of an IRB continuing review approval letter, all activities involving human subjects (e.g., recruitment, consenting, study procedures), and further data collection and analysis must cease.

☒ None

If the project expires prior to receipt of an IRB continuing review approval letter, all activities involving human subjects (e.g., recruitment, consenting, study procedures), and further data collection and analysis must cease.