



## MEMORANDUM

**DATE:** February 2, 2012

**TO:** Urs Kurt Buehlmann, Mathias Schmitt

**FROM:** Virginia Tech Institutional Review Board (FWA00000572, expires May 31, 2014)

**PROTOCOL TITLE:** Impact of Leadership Practices on Hospital Performance

**IRB NUMBER:** 12-063

Effective February 1, 2012, the Virginia Tech IRB Chair, Dr. David M. Moore, 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: **2/1/2012**

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 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?
1/31/2012	09071810	Lean Management Institute	Not Required (not federally funded)

\*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](mailto:irbadmin@vt.edu)) immediately.

cc: File



## MEMORANDUM

**DATE:** July 29, 2011

**TO:** Urs Kurt Buehlmann, Mathias Schmitt

**FROM:** Virginia Tech Institutional Review Board (FWA00000572, expires May 31, 2014)

**PROTOCOL TITLE:** Impact of Leadership Practices on Hospital Performance

**IRB NUMBER:** 11-643

Effective July 29, 2011, the Virginia Tech IRB Chair, Dr. David M. Moore, 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: **Expedited, under 45 CFR 46.110 category(ies) 5, 7**

Protocol Approval Date: **7/29/2011**

Protocol Expiration Date: **7/28/2012**

Continuing Review Due Date\*: **7/14/2012**

\*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?
7/25/2011	09071810	Lean Management Inst.	Not Required (not federally funded)

\*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](mailto:irbadmin@vt.edu)) immediately.

cc: File

## Timo Grueneberg

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**From:** John O'Donnell <jodonnell@lean.org>  
**Sent:** Friday, July 08, 2011 6:18 PM  
**To:** Mathias Schmitt; John Y Shook  
**Subject:** RE: Healthcare Survey

Hi Mathias,

Sorry for the delay – a very busy week at LEI.

It is OK for you to use the questions based on Jim's LM vs. MM hypotheses. One thought for consideration.....the way you have the questions listed it might be easy for someone to figure out the pattern – one represents 'good' behavior; one 'bad' behavior. When we use these distinctions in a survey we mix them up so they don't follow a discernable pattern

Good luck with the research.

Best regards,

John

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**From:** Mathias Schmitt [<mailto:mathi.schmitt@gmail.com>]  
**Sent:** Thursday, July 07, 2011 8:19 AM  
**To:** John Y Shook; John O'Donnell  
**Cc:** Mathias Schmitt  
**Subject:** Healthcare Survey

Dear John,

I hope these lines find you well!

Just to follow up on my email from last week ... I have attached the most recent version of the healthcare survey (including Jim's survey question about process vs. modern management).

**Would you please let me know whether I can use those questions or not – please see question 11 of the attached document?** Do I have to contact Jim directly? Can we have phone call on short notice?

I just do not want to go ahead without approval!!!

Here are the next steps for the research:

- **Background information –**
  - the questionnaire was developed based on feedback and conversations with a couple of LGN affiliates, hospital representatives of hospitals mainly in VA and CA (HCA, Carillion, UC Davis, etc.), U.S. health initiative, and researchers at VT and the Ohio State.
  - Qualtrics (an online survey tool) was chosen to be used for the survey ... still waiting for the license
- After approval/deny of using Jim's questions, the questionnaire will be send out to many of the **LGN affiliates for feedback** (you, Dan, Michael, Rene, Flavio, Oriol, Peter, Helen, Roberto, Ian, Marc, etc.) – due date for final feedback is scheduled for Wednesday, 13 of July, 2011

- **Survey questionnaire will be send out** (letter with url/link to the online survey) to 4795 hospitals here in the US on **Monday July, 18<sup>th</sup> 2011** after review and approval by IRB, you, and my committee members including Rene. THIS WILL BE AN ONLINE SURVEY – the survey will be distributed via mail, email, social media, announcements in newsletters and magazines.
- The **results of the primary and secondary data** (CMS database, AHA database, and survey results) analysis will allow us to identify 2-3 high performance hospitals and 2-3 low performance hospitals. The **executives of those hospitals then will be interviewed (qualitative research)** to verify if leadership has an impact on successful transformations in healthcare.

I hope this gives you some insights into the research project! **Please let me know if I can use Jim’s questionnaire to be included in my survey** – I definitely will give credit in my dissertation for that.

Your help is greatly appreciated and I look forward to hearing from you soon.

Best regards,

Mathias