



Mary-Ann Winkelmes <mary-ann.winkelmes@unlv.edu>

IRBNet message from Cindy Lee-Tataseo

1 message

Cindy Lee-Tataseo <no-reply@irbnet.org>

Thu, Oct 27, 2016 at 4:07 PM

Reply-To: Cindy Lee-Tataseo <cindy.lee-tataseo@unlv.edu>

To: Mary-Ann Winkelmes <mary-ann.winkelmes@unlv.edu>

Message from Cindy Lee-Tataseo:

Re: [711238-11] Transparency in Learning and Teaching Initiative

Dr. Winkelmes,

Thank you for your submission on 10/26/16 regarding the referenced project. The information has been reviewed and no further information is needed. You may continue with the research with the changes listed in this request. For future changes to this protocol, please send a quick project mail to our office. We will review these changes for a change in review type. If the research remains exempt, we will reply to your IRBNet message letting you know no further information is needed.

Please let me know if you have any questions.

Thank you,
Cindy Lee-Tataseo

UNLV

Modification Request Form

Instructions:

1. Complete all sections of this form.
2. Submit all previously submitted documents that contain information affected by the modification(s).

Note:

1. Handwritten and hand delivered forms **will not** be accepted.
2. INCOMPLETE FORMS WILL BE RETURNED.
3. Modification may not be implemented until you have received notification of IRB approval.
4. For your records, it is important that you keep a copy of this completed form.

General Information

Submittal Date: 10/25/2016 Principal Investigator Name: Mary-Ann Winkelmes
Protocol Title: Transparency in Learning and Teaching in Higher Education
Protocol Number: 711238-8 Last Approval Date: 7/28/2016
Prior Approval: Expedited Review Full Board Review Exempt

Description of Modification

Type of Modification (check all that apply):

- | | |
|---|--|
| <input type="checkbox"/> Currently approved procedure | <input type="checkbox"/> Informed Consent |
| <input type="checkbox"/> Number of subjects | <input type="checkbox"/> Survey/Questionnaire |
| <input type="checkbox"/> Research Team** | <input checked="" type="checkbox"/> Other (e.g., advertisement, flyer, etc.) |
| <input type="checkbox"/> Title | |

Modification Summary

Briefly describe the modification.

We are requesting to add several new research team members from UNLV's Psychology Department: Professor Rachael Robnett and graduate students Sarah Thoman and Jennifer Buck. In addition, we are requesting to follow the process approved on April 18, 2016 (attached) with one change: we will run the 7or10-question survey in WMST113 in the Fall of 2016 before the WMST113 students complete the Transparency Survey at the end of term. Students will be invited to take the 7or10-question survey via an email from the course instructor (attached). The 7or10 question survey can be viewed by clicking the URL in the attached email invitation from the course instructor.

**Note: Addition of research team must include name(s) and role(s). Change in PI must be submitted and signed by the original PI on the protocol. Include the reason for the change in the modification summary.

Reanalysis of Risk (check one)

- This modification **does not** increase risk to participants enrolled in this study.
 This modification **does** increase risk to participants enrolled in this study.

Signatures of Assurance

A. Investigator's Assurance:

I certify that the information provided in this application is complete and accurate. As Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations designated by the IRB. I agree to comply with all UNLV policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Performing the project by qualified personnel according to the approved protocol.
- Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting adverse events to the ORI – Human Subjects in writing according to IRB guidelines.
- Arranging for a co-investigator to assume direct responsibility, if the PI will be unavailable to direct this research personally, as when on sabbatical leave or vacation.

*****FACULTY ADVISOR (IF APPLICABLE):** By my signature as Principal Investigator on this research application, I certify that the student/fellow investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to act as the liaison between the IRB and the student/fellow investigator with all written and verbal communications.
- I agree to meet with the student/fellow investigator on a regular basis to monitor the progress of the study.
- I agree to be available and to personally supervise the student/fellow investigator in solving problems, as they arise.
- I assure that the student/fellow investigator will promptly report adverse events to the ORI – Human Subjects according to IRB guidelines.
- I will arrange for an alternate faculty advisor to assume responsibility if I become unavailable, as when on sabbatical leave or vacation.
- I assure that the student/fellow investigator will follow through with the storage and destruction of data as outlined in the protocol.

By submitting this form electronically, I agree to the assurance as stated above.



Additional Research Team Members Form

Instructions:

1. Complete all sections of this form.
2. INCOMPLETE FORMS WILL BE RETURNED.

1. General Information

Research Protocol Title: Transparency in Learning and Teaching in Higher Education (TILT Higher Ed)

Principal Investigator: Mary-Ann Winkelmes

2. Research Team Members: *List all research team members (including PI) who will have contact with subjects, have contact with subjects' data or biological samples, or use subjects' personal information.*

NAME and DEPARTMENT	ROLE IN PROTOCOL	SPECIFIC EXPERIENCE WITH ROLE IN PROTOCOL	ROLE IN CONSENT PROCESS
EXAMPLE: Dr. Chris Researcher, Research Department	EXAMPLE: Developed protocol, collecting data, analyzing data, writing report	EXAMPLE: Has had previous research studies with human subjects	EXAMPLE: Recruiting subjects, writing the consent form, consenting subjects, answering questions
Dr. Rachael Robnett, Psychology Dept, UNLV	consultant, analysis of de-identified data	previous research studies with human subjects	none
Sarah Thoman, graduate student, Psychology Dept, UNLV	analysis of de-identified data	previous research studies with human subjects, previous psychometric analysis studies of survey tools	none
Jennifer Buck, graduate student, Psychology Dept, UNLV	analysis of de-identified data	previous research studies with human subjects	none

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Jennifer Buck (ID: 5810017)
- **Email:** buckj1@unlv.nevada.edu
- **Institution Affiliation:** University of Nevada, Las Vegas (ID: 418)
- **Institution Unit:** Psychology
- **Phone:** 6303357681

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 2. Social/Behavioral IRB
- **Stage:** Stage 1 - Basic Course
- **Description:** If you have any questions regarding your requirements you may contact the UNLV OPRS by phone at 702.895.2794 or by email at OPRSHumanSubjects@unlv.edu

- **Report ID:** 20831003
- **Completion Date:** 13-Sep-2016
- **Expiration Date:** 12-Sep-2021
- **Minimum Passing:** 75
- **Reported Score*:** 89

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	11-Sep-2016	3/3 (100%)
History and Ethical Principles - SBE (ID: 490)	11-Sep-2016	4/5 (80%)
Defining Research with Human Subjects - SBE (ID: 491)	11-Sep-2016	4/5 (80%)
The Federal Regulations - SBE (ID: 502)	11-Sep-2016	4/5 (80%)
Assessing Risk - SBE (ID: 503)	11-Sep-2016	5/5 (100%)
Informed Consent - SBE (ID: 504)	12-Sep-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	12-Sep-2016	4/5 (80%)
Research with Prisoners - SBE (ID: 506)	12-Sep-2016	4/5 (80%)
Research with Children - SBE (ID: 507)	13-Sep-2016	4/5 (80%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	13-Sep-2016	5/5 (100%)
International Research - SBE (ID: 509)	13-Sep-2016	4/5 (80%)
Internet-Based Research - SBE (ID: 510)	13-Sep-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	13-Sep-2016	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	13-Sep-2016	4/5 (80%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	13-Sep-2016	3/3 (100%)
UNLV (ID: 697)	13-Sep-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: <https://www.citiprogram.org/verify/?96ba79cb-286c-4145-876b-4abefd590a4f>

CITI Program

Email: support@citiprogram.org

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Jennifer Buck (ID: 5810017)
- **Email:** buckj1@unlv.nevada.edu
- **Institution Affiliation:** University of Nevada, Las Vegas (ID: 418)
- **Institution Unit:** Psychology
- **Phone:** 6303357681

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 2. Social/Behavioral IRB
- **Stage:** Stage 1 - Basic Course
- **Description:** If you have any questions regarding your requirements you may contact the UNLV OPRS by phone at 702.895.2794 or by email at OPRSHumanSubjects@unlv.edu

- **Report ID:** 20831003
- **Report Date:** 13-Sep-2016
- **Current Score**:** 89

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethical Principles - SBE (ID: 490)	11-Sep-2016	4/5 (80%)
Defining Research with Human Subjects - SBE (ID: 491)	11-Sep-2016	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	11-Sep-2016	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	11-Sep-2016	4/5 (80%)
Assessing Risk - SBE (ID: 503)	11-Sep-2016	5/5 (100%)
Informed Consent - SBE (ID: 504)	12-Sep-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	12-Sep-2016	4/5 (80%)
Research with Prisoners - SBE (ID: 506)	12-Sep-2016	4/5 (80%)
Research with Children - SBE (ID: 507)	13-Sep-2016	4/5 (80%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	13-Sep-2016	5/5 (100%)
International Research - SBE (ID: 509)	13-Sep-2016	4/5 (80%)
Internet-Based Research - SBE (ID: 510)	13-Sep-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	13-Sep-2016	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	13-Sep-2016	4/5 (80%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	13-Sep-2016	3/3 (100%)
UNLV (ID: 697)	13-Sep-2016	No Quiz

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Verify at: <https://www.citiprogram.org/verify/?96ba79cb-286c-4145-876b-4abefd590a4f>

Collaborative Institutional Training Initiative (CITI Program)

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Phone: 888-529-5929

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sarah Thoman (ID: 5049501)
- **Email:** thoman@unlv.nevada.edu
- **Institution Affiliation:** University of Nevada, Las Vegas (ID: 418)
- **Institution Unit:** Psychology
- **Phone:** 7742536034

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 2. Social/Behavioral IRB
- **Stage:** Stage 1 - Basic Course
- **Description:** If you have any questions regarding your requirements you may contact the UNLV OPRS by phone at 702.895.2794 or by email at OPRSHumanSubjects@unlv.edu

- **Report ID:** 17188052
- **Completion Date:** 09/09/2015
- **Expiration Date:** 09/07/2020
- **Minimum Passing:** 75
- **Reported Score*:** 93

REQUIRED AND ELECTIVE MODULES ONLY

DATE COMPLETED

Belmont Report and CITI Course Introduction (ID: 1127)	09/07/15
History and Ethical Principles - SBE (ID: 490)	09/07/15
Defining Research with Human Subjects - SBE (ID: 491)	09/07/15
The Federal Regulations - SBE (ID: 502)	09/07/15
Assessing Risk - SBE (ID: 503)	09/08/15
Informed Consent - SBE (ID: 504)	09/08/15
Privacy and Confidentiality - SBE (ID: 505)	09/08/15
Research with Prisoners - SBE (ID: 506)	09/08/15
Research with Children - SBE (ID: 507)	09/08/15
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	09/08/15
International Research - SBE (ID: 509)	09/08/15
Internet-Based Research - SBE (ID: 510)	09/09/15
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	09/09/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	09/09/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	09/09/15
UNLV (ID: 697)	09/09/15

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program

Email: citisupport@miami.edu

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sarah Thoman (ID: 5049501)
- **Email:** thoman@unlv.nevada.edu
- **Institution Affiliation:** University of Nevada, Las Vegas (ID: 418)
- **Institution Unit:** Psychology
- **Phone:** 7742536034

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 2. Social/Behavioral IRB
- **Stage:** Stage 1 - Basic Course
- **Description:** If you have any questions regarding your requirements you may contact the UNLV OPRS by phone at 702.895.2794 or by email at OPRSHumanSubjects@unlv.edu

- **Report ID:** 17188052
- **Report Date:** 09/09/2015
- **Current Score**:** 93

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES

MOST RECENT

History and Ethical Principles - SBE (ID: 490)	09/07/15
Defining Research with Human Subjects - SBE (ID: 491)	09/07/15
Belmont Report and CITI Course Introduction (ID: 1127)	09/07/15
The Federal Regulations - SBE (ID: 502)	09/07/15
Assessing Risk - SBE (ID: 503)	09/08/15
Informed Consent - SBE (ID: 504)	09/08/15
Privacy and Confidentiality - SBE (ID: 505)	09/08/15
Research with Prisoners - SBE (ID: 506)	09/08/15
Research with Children - SBE (ID: 507)	09/08/15
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	09/08/15
International Research - SBE (ID: 509)	09/08/15
Internet-Based Research - SBE (ID: 510)	09/09/15
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	09/09/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	09/09/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	09/09/15
UNLV (ID: 697)	09/09/15

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Rachael Robnett (ID: 3528527)
- **Email:** rachael.robnett@unlv.edu
- **Institution Affiliation:** University of Nevada, Las Vegas (ID: 418)
- **Institution Unit:** Psychology
- **Phone:** 702-895-5595

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 2. Social/Behavioral IRB
- **Stage:** Stage 1 - Basic Course
- **Description:** If you have any questions regarding your requirements you may contact the UNLV OPRS by phone at 702.895.2794 or by email at OPRSHumanSubjects@unlv.edu

- **Report ID:** 11955600
- **Completion Date:** 12/20/2013
- **Expiration Date:** 12/19/2018
- **Minimum Passing:** 75
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY

DATE COMPLETED

Introduction (ID: 757)	12/20/13
History and Ethical Principles - SBE (ID: 490)	12/20/13
Defining Research with Human Subjects - SBE (ID: 491)	12/20/13
The Federal Regulations - SBE (ID: 502)	12/20/13
Assessing Risk - SBE (ID: 503)	12/20/13
Informed Consent - SBE (ID: 504)	12/20/13
Privacy and Confidentiality - SBE (ID: 505)	12/20/13
Research with Prisoners - SBE (ID: 506)	12/20/13
Research with Children - SBE (ID: 507)	12/20/13
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	12/20/13
International Research - SBE (ID: 509)	12/20/13
Internet-Based Research - SBE (ID: 510)	12/20/13
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	12/20/13
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	12/20/13
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	12/20/13
UNLV (ID: 697)	12/20/13

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Rachael Robnett (ID: 3528527)
- **Email:** rachael.robnett@unlv.edu
- **Institution Affiliation:** University of Nevada, Las Vegas (ID: 418)
- **Institution Unit:** Psychology
- **Phone:** 702-895-5595

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 2. Social/Behavioral IRB
- **Stage:** Stage 1 - Basic Course
- **Description:** If you have any questions regarding your requirements you may contact the UNLV OPRS by phone at 702.895.2794 or by email at OPRSHumanSubjects@unlv.edu

- **Report ID:** 11955600
- **Report Date:** 04/29/2015
- **Current Score**:** 94

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES

MOST RECENT

Introduction (ID: 757)	12/20/13
History and Ethical Principles - SBE (ID: 490)	12/20/13
Defining Research with Human Subjects - SBE (ID: 491)	12/20/13
The Federal Regulations - SBE (ID: 502)	12/20/13
Assessing Risk - SBE (ID: 503)	12/20/13
Informed Consent - SBE (ID: 504)	12/20/13
Privacy and Confidentiality - SBE (ID: 505)	12/20/13
Research with Prisoners - SBE (ID: 506)	12/20/13
Research with Children - SBE (ID: 507)	12/20/13
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	12/20/13
International Research - SBE (ID: 509)	12/20/13
Internet-Based Research - SBE (ID: 510)	12/20/13
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	12/20/13
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	12/20/13
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	12/20/13
UNLV (ID: 697)	12/20/13

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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Dear Students:

Please help your instructors to study and improve the quality of students' experiences in this course. Your responses to the following 1-minute online survey will inform improvements to this course and others like it at UNLV and across the U.S. Please [click here to take the survey](#), or enter <http://tinyurl.com/hnxa29u> in your browser.

Thank you for your important input.

Sincerely,

[Mary-Ann Winkelmes](#), Ph.D.

Principal Investigator, [Transparency in Learning and Teaching Project](#)

Coordinator of Instructional Development and Research

Associate Graduate Faculty, History Department

University of Nevada, Las Vegas

4505 S. Maryland Parkway, Mail Code 1014

Las Vegas, NV 89154-1014

Phone: [\(702\) 895-4832](tel:7028954832) Fax: [702-895-3455](tel:7028953455)

Senior Fellow, Association of American Colleges & Universities

Nevada Humanities Board of Trustees Member

UNLV

Modification Request Form

Instructions:

1. Complete all sections of this form.
2. Submit all previously submitted documents that contain information affected by the modification(s).

Note:

1. Handwritten and hand delivered forms **will not** be accepted.
2. INCOMPLETE FORMS WILL BE RETURNED.
3. Modification may not be implemented until you have received notification of IRB approval.
4. For your records, it is important that you keep a copy of this completed form.

General Information

Submittal Date: 4/06/2016 Principal Investigator Name: Mary-Ann Winkelmes
Protocol Title: Transparency in Learning and Teaching project
Protocol Number: 1305-4474 Last Approval Date: _____
Prior Approval: Expedited Review Full Board Review Exempt

Description of Modification

Type of Modification (check all that apply):

- | | |
|--|---|
| <input checked="" type="checkbox"/> Currently approved procedure | <input type="checkbox"/> Informed Consent |
| <input type="checkbox"/> Number of subjects | <input checked="" type="checkbox"/> Survey/Questionnaire |
| <input type="checkbox"/> Research Team** | <input type="checkbox"/> Other (e.g., advertisement, flyer, etc.) |
| <input type="checkbox"/> Title | |

Modification Summary

Briefly describe the modification.

We wish to send up to 10 additional survey questions to some students who complete the already-approved Transparency in Learning and Teaching Survey in May, 2016. These additional survey questions will allow us to understand more about two critical findings that the Transparency Project has already studied and published: students' sense of confidence and sense of belonging. Specifically, Katharine Johnson, the COLA100E instructor/supervisor, will send all COLA100E students a URL that invites them to complete the additional survey questions after they complete the Transparency Survey. The survey software will randomly decide whether the students receive 7 or 10 survey questions. Students' ID numbers will be gathered and students will be assigned a random identifier by the software. PI Mary-Ann Winkelmes will retain the key (to enable connection of students' Transparency Survey responses with those from the 7 or 10 question survey). The survey questions and the Information and Consent statement are attached. Note that the Information and Consent statement is the same one already approved for the Transparency Project [Protocol 1305-4474] (with the amount of time changed and highlighted in yellow) and the additional survey questions are a subset of those already approved for the Locus of Control survey [Protocol 835605-1] conducted by a Transparency Project research team member, Jeffrey Butler.

**Note: Addition of research team must include name(s) and role(s). Change in PI must be submitted and signed by the original PI on the protocol. Include the reason for the change in the modification summary.

Reanalysis of Risk (check one)

- This modification **does not** increase risk to participants enrolled in this study.

This modification *does* increase risk to participants enrolled in this study.

Signatures of Assurance

A. Investigator's Assurance:

I certify that the information provided in this application is complete and accurate. As Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations designated by the IRB. I agree to comply with all UNLV policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Performing the project by qualified personnel according to the approved protocol.
- Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting adverse events to the ORI – Human Subjects in writing according to IRB guidelines.
- Arranging for a co-investigator to assume direct responsibility, if the PI will be unavailable to direct this research personally, as when on sabbatical leave or vacation.

*****FACULTY ADVISOR (IF APPLICABLE):** By my signature as Principal Investigator on this research application, I certify that the student/fellow investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to act as the liaison between the IRB and the student/fellow investigator with all written and verbal communications.
- I agree to meet with the student/fellow investigator on a regular basis to monitor the progress of the study.
- I agree to be available and to personally supervise the student/fellow investigator in solving problems, as they arise.
- I assure that the student/fellow investigator will promptly report adverse events to the ORI – Human Subjects according to IRB guidelines.
- I will arrange for an alternate faculty advisor to assume responsibility if I become unavailable, as when on sabbatical leave or vacation.
- I assure that the student/fellow investigator will follow through with the storage and destruction of data as outlined in the protocol.

By submitting this form electronically, I agree to the assurance as stated above.