# Modification to Protocol #1305-4474: Transparency in Learning...

Inbox x

**OPRS Human Subjects <irb@unlv.edu> (sent by christa.esparza@unlv.edu)**

Nov 26, 2014

to me

Dr. Winkelmes,

Thank you for your recent submission regarding the protocol named above. The information has been reviewed and no further information is needed. You may continue with the research with the changes listed in your modification request. For future modifications to this protocol, please send a quick email to our office. We will review the modifications for a change in review type. If the research remains exempt, we will file your information and no formal notification will be sent (only an email).

Please let me know if you have any questions.

Thank you,

Christa Esparza
Human Research Coordinator
Office of Research Integrity - Human Subjects
University of Nevada, Las Vegas
4505 Maryland Parkway  Box 451047
Las Vegas, NV  89154-1047
Main: (702) 895-2794  Fax:  (702) 895-0805
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Website: http://research.unlv.edu/ORI-HSR/

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Office of Research Integrity
Human Subjects

| IRB Received Date Stamp— Office Use Only | IRB Protocol Number— Office Use Only |
|---|---|
| RECEIVED NOV 07 2014 | 1305-4474 |

# Modification Request Form

## General Information

**Submittal Date:**
**PI Name:** Dr. Mary-Ann Winkelmes Ph.D.
**Protocol Title:** Transparency in Learning and Teaching Initiative
**Protocol Number:** 1305-4474

## Description of Modification

**Type of Modification** ***(check all that apply)*****:**

- ☑ Currently approved procedure ☑ Informed Consent
- ☐ Number of subjects ☑ Survey/Questionnaire
- ☐ Research Team** ☐ Other ***(e.g., advertisement, flyer, etc.)***
- ☐ Title

## Modification Summary

### Proposed revisions to IRB-approved Transparency Online Survey:

Two revisions are proposed to the IRB-approved Transparency Online Survey. These revisions aim to accomplish two goals: 1) align survey questions with US Department of Education and US Census Department standards; 2) correct minor weaknesses identified by a psychometric study conducted in spring 2014 by Matt Bernacki, Caleb Picker, Tondra De and Mary-Ann Winkelmes.

add one administration of the Transparency Online Survey at the beginning of each term, to provide "before" data to compare with the "after" data already gathered by the IRB-approved students' end-of-term Transparency Online Survey (Both administrations of the survey would continue to follow the IRB-approved, voluntary, 6-7-minute online format in which students may skip any questions.)
adjust a handful of survey questions as indicated in Table 1 (attached).

### Proposed revision to IRB-approved data gathering:

The aim of this revision is to reduce the workload on UNLV staff members by assigning already IRB-approved tasks to Transparency Project team members. The proposed revision is that Principal Investigator Mary-Ann Winkelmes will perform the following IRB-approved tasks currently performed by UNLV staff members:

35022

Lindsay Couzens and Chris Heavey in the General Education office will submit a *Focus Request* [https://apps.ess.unlv.edu/helprequest/] for demographic and semester grade data about a group of approximately 600 students who completed the Survey. Lindsay Couzens will provide the Registrar's Office with NSHE numbers for this Focus Request. Once Lindsay receives the data from the Registrar's Office, she will connect it in a spreadsheet to those students' Survey responses. She will assign a randomized, anonymous, de-identified number to each students' responses in the spreadsheet and then remove the students' NSHE numbers.

If approved, this revision would require a small revision to the already IRB-approved Information and Consent Statement that appears at the beginning of the online Survey. The proposed revision is indicated in red in the attached document, "IRB-approved Info and Consent Statement with proposed changes in red."

**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.

Please ensure your Supporting Documents have been added through the Protocol Summary Page (button on the left), and send your Modification by clicking the Send button from your Home Page.

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# Exempt Research Application Form

## Applicable Policy – 45 CFR 46.101 (b)

Instructions:
CITI certification (*www.citiprogram.org*) must be current at the time of protocol submission.
Complete this application if you believe your study qualifies as exempt research based on the categories below. The UNLV IRB will make the final determination of exempt research projects. The exempt determination must be granted in writing by the UNLV IRB before research can begin on the project.
Exempt research must adhere to the same ethical principles governing all research.
Exempt applications must include copies of informed consent, questionnaires/surveys, advertisements, etc.
If the IRB determines the research to be non-exempt, the project must be resubmitted with the completed Research Protocol Proposal Form to again proceed through the IRB review process.

**1.a Duration of Study**

Anticipated Time to Complete the Study: 5 years

**1.b Research Protocol Title**

Transparency in Learning and Teaching Initiative

**2. Investigator's Contact Information**

***(The PI must be UNLV faculty in all cases involving studies carried out by students or fellows.)***

Name and Credentials:
Dr. Mary-Ann Winkelmes Ph.D.

Department/ Institution: University of Nevada, Las Vegas Mail Stop: Mail Code 1014 Main Phone: (702) 895-4832
Ext:

Email: Mary-Ann.Winkelmes@unlv.edu

**3. Student/Fellow Investigator**

3.1 Is there a Student Researcher who is conducting this research as a basis for their dissertation or thesis?

- ○ Yes
- ◉ No

**4. Protocol Coordinator**

**5. Co- Principal Investigators**

**6. Research Team Members:**

Name and Credentials:
Dr. Matthew Bernacki Ph.D.

Department/ Institution: College of Education Mail Stop: Main Phone: (702) 895-4013 Ext:

Email: matt.bernacki@unlv.edu

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Name and Credentials:
Ms. Tondra De BS, ABD

Department/ Institution: UNLV, Office of Decision Support Mail Stop: Main Phone: Ext:

Email: tondrade@yahoo.com

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Name and Credentials:
Mr. Justin Lewis BS

Department/ Institution: UNLV Mail Stop: Main Phone: Ext:

Email: lewisj2@unlv.nevada.edu

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## 7. Risk Assessment

7.1 In order for your study to qualify as exempt, it may only involve minimal risk. By Federal Regulations at 45CFR46.102(i), *"Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

Does your study meet the definition of minimal risk as defined above? ◉ Yes ○ No

Describe the risks to project participants ***(e.g., breach of confidentiality)*** and explain how they will be minimized, this should include a description regarding how participants' confidentiality will be protected ***(e.g., data collected for the study will be kept on a password protected desktop computer in a locked office)***
No identifiers will be gathered from student participants. All student participants remain completely anonymous. Identities of faculty participants will be kept confidential and stored on a password protected computer in a locked office and on a backup drive kept in a locked cabinet.

## 8. Category of Exemption

Please indicate your exemption category choice by completing the relevant categories from the list below. *As you check the appropriate boxes, the form will guide you on the Category your study may qualify. Please note: The Federal regulations do not permit any new categories and only the IRB may determine which research activities qualify for an exempt review.*

Key: Solid box All items in the box must be true | Dotted box: One item in the box must be true

**Category 1** ***(All of the following are true)*:**

- [x] Research conducted in established or commonly accepted educational settings
- [x] This research involves normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
- [x] The research is **NOT** subject to FDA regulation ***(e.g.; drug, devices, or biologics)***
- [x] The research does **NOT** involve prisoners as participants

**YOUR STUDY MAY QUALIFY FOR CATEGORY 1.** *Please check here* [x] *and complete the rest of this application.*

**Category 2** ***(All of the following are true)*:**

This research involves the use of one or more of the following:

**YOU CHECKED ONE OF THE FOLLOWING.** *Please check this box.* [x]

- [ ] Educational tests ***(cognitive, diagnostic, aptitude, achievement)***
- [x] Survey procedures
- [x] Interview procedures
- [ ] Observation of public behavior

When the research involves children as participants, the procedures are limited to:

- [ ] Educational tests ***(cognitive, diagnostic, aptitude, achievement)***
- [ ] Observation of public behavior where the investigator(s) will **NOT** participate in the activities being observed

Information obtained is recorded in such a manner that either:

**YOU CHECKED ONE OF THE FOLLOWING.** *Please check this box.* [x]

- [x] Participants **CANNOT** be identified, directly or through identifiers linked to the participants.

Both of the following are true:

**YOU CHECKED BOTH OF THE FOLLOWING.** *Please check this box.* [x]

- [x] Participants **CAN** be identified, directly or through identifiers linked to the participants.
- [x] Any disclosure of the participants' responses outside the research could **NOT** reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

- [x] The research is **NOT** subject to FDA regulation ***(e.g.; drug, devices, or biologics)***
- [x] The research does **NOT** involve prisoners as participants

**Category 3** ***(All of the following are true)*:**

- [ ] The research is **NOT** exempt under Category 2 above (Research cannot qualify for both Category 2 and Category 3)

The research involves the use of one or more of the following:

**YOU CHECKED ONE OF THE FOLLOWING.** *Please check this box.* [ ]

- [ ] Educational tests ***(cognitive, diagnostic, aptitude, achievement)***
- [ ] Survey procedures
- [ ] Interview procedures
- [ ] Observation of public behavior

Either of the following is true:

**YOU CHECKED ONE OF THE FOLLOWING.** *Please check this box.* [ ]

- [ ] The participants are elected or appointed public officials or candidates for public office

☐ Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

☐ The research is **NOT** subject to FDA regulation ***(e.g.; drug, devices, or biologics)***

☐ The research does **NOT** involve prisoners as participants

**YOUR STUDY MAY QUALIFY FOR CATEGORY 3.** *Please check here* ☐ *and complete the rest of this application.*

**Category 4** ***(All of the following are true)*:**

☐ The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens ***(i.e., the reviewed materials currently exist and are NOT prospectively collected). Indicate in protocol the data collection date range.***

At least one of the following is true:

**YOU CHECKED ONE OF THE FOLLOWING.** *Please check this box.* ☐

☐ These sources are publicly available

Information is recorded in such a manner that both of the following are true:

**YOU CHECKED BOTH OF THE FOLLOWING.** *Please check this box.* ☐

☐ Participants cannot be directly identified

☐ Participants cannot be identified through identifiers linked to them

☐ The research is **NOT** subject to FDA regulation ***(e.g.; drug, devices, or biologics)***

☐ The research does **NOT** involve prisoners as participants

**YOUR STUDY MAY QUALIFY FOR CATEGORY 4.** *Please check here* ☐ *and complete the rest of this application.*

**Category 5** ***(All of the following are true)*:**

☐ The project is a research or demonstration project

☐ The project is conducted by or subject to the approval of Department or Agency heads

☐ The project is designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs

☐ The program under study delivers a public benefit ***(e.g., financial or medical benefits as provided under the Social Security Act)*** or service ***(e.g., social, supportive, or nutrition services as provided under the Older Americans Act)***

☐ The project is conducted pursuant to specific federal statutory authority

☐ There is no statutory requirement that an IRB review the project

☐ The project does not involve significant physical invasions or intrusions upon the privacy of participants

☐ The research is **NOT** subject to FDA regulation ***(e.g.; drug, devices, or biologics)***

☐ The research does **NOT** involve prisoners as participants

**YOUR STUDY MAY QUALIFY FOR CATEGORY 5.** *Please check here* ☐ *and complete the rest of this application.*

**Category 6** ***(All of the following are true)*:**

☐ The research involves a taste and food quality evaluation and consumer acceptance studies

One of the following is true:

**YOU CHECKED ONE OF THE FOLLOWING.** *Please check this box.* ☐

☐ Wholesome foods without additives will be consumed

A food will be consumed that contains a food ingredient and both of the following are true:

YOU CHECKED BOTH OF THE FOLLOWING. *Please check this box.* ☐

- ☐ The food ingredient is at or below the level to be safe
- ☐ The food ingredient is for a use found to be safe

A food will be consumed that contains an agricultural chemical or environmental contaminant and one of the following is true:

YOU CHECKED ONE OF THE FOLLOWING. *Please check this box.* ☐

- ☐ The agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration
- ☐ The agricultural chemical or environmental contaminant is at or below the level approved by the Environmental Protection Agency
- ☐ The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety and Inspection Service of the U.S. Department of Agriculture

☐ The research is **NOT** subject to FDA regulation ***(e.g.; drug, devices, or biologics)***

☐ The research does **NOT** involve prisoners as participants

YOUR STUDY MAY QUALIFY FOR CATEGORY 6. *Please check here* ☐ *and complete the rest of this application.*

**9. 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. If needed, see the Additional Research Team Member Form.*

| 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 7 years of conducting and publishing human subjects research at a university | EXAMPLE: Recruiting subjects, writing the consent form, consenting subjects, answering questions |
| Dr. Mary-Ann Winkelmes Ph.D. University of Nevada, Las Vegas | Developed protocol, gather data, analyze data, write reports | Five years' experience conducting and publishing humas subjects research at a university (http://www.teachingandlearning.illinois.edu/transparency.html) | Writing consent form, recruiting subjects |
| Dr. Matthew Bernacki Ph.D. College of Education | advisor | advisor | none |
| Ms. Tondra De BS, ABD UNLV, Office of Decision Support | advisor | helped to construct dataset, helped to format charts and slides to illustrate findings | none |
| Mr. Justin Lewis BS UNLV | Graduate Assistant | data analysis, preparation of charts and reports | none |

## 10. Project Details

A. Describe the purpose of the project and how you will conduct it: Clearly describe any procedures to be used during the conduct of the study. In addition, describe the recruitment process and include copies of all recruitment materials to be used for this study

The Transparency in Learning and Teaching Initiative is a study that aims to gather and disseminate (via reports and publications) anonymous, aggregate information about how higher education students understand their own learning processes and how instructors can enhance that understanding. The Illinois Initiative on Transparency in Learning and Teaching provides a structure for faculty who wish to contribute to a large and significant research project on students' learning, while relying on others to provide the education-research expertise and administrative support. It also brings teachers and students into dialogue about the processes of teaching and learning. Ultimately, this research will identify which small changes to teaching and learning practices produce the greatest beneficial impact on students%u2019 learning, with results specific to: the past experience of the student, the size of the course, the level of the course (beginning college through advanced degree) and the discipline. Longer-term results may include higher retention and graduation rates for undergraduate students, including community college students who transfer into four-year institutions, and greater participation of diversely prepared students in Masters and PhD degree programs. Participants will be students enrolled in the courses of voluntarily participating instructors. Students will receive an emailed invitation from their instructor to complete a four-to-five-minute online survey. Instructor participants are those who volunteer to participate because they have heard about the project from colleagues or from the project's investigators or from the project's website, publications, or conference presentations. All potential student participants will receive an electronic invitation from the principal investigator and/or course instructor during the last week their participating course is in session. Clicking on a link provided in the invitation will lead a student to an Information and Consent form (below). After acknowledging they have read and understood the information and consent information, students will advance to the online survey. Students who agree to participate will complete an online survey (attached) of approximately thirty multiple-choice questions about their perceptions of their learning experience in the course. The survey takes approximately four or five minutes to complete. Instructor participants register online to indicate their voluntary participation. Information and Consent forms for participating instructors (below) allow for future reporting of anonymous data in the aggregate about how instructors describe their teaching on the registration form, or in any optional conversations online, by telephone or in person. Instructor participants will invite their students to complete an online survey at the end of the course. Instructors in the control group will make no changes to their teaching, while instructors in the "transparency" group may choose to make one of several small alteration to their teaching technique that the project has demonstrated as statistically significant for enhancing students' learning (Winkelmes, "Transparency in Teaching: Faculty Share Data and Improve Students' Learning," Liberal Education, Spring 2013, Vol. 99, No. 2). Instructor participants will be invited by the principal investigator to complete a feedback form online after their participation (attached), that will take approximately three minutes to complete. Data gathered by this project will be analyzed and shared (anonymously and in the aggregate) via reports, presentations and publication.

B. Maximum number of subjects: The project has alre

C. Describe study population/specimens/data to be studied ***(e.g., healthy adults age 18-45)***. . *Please note that research involving prisoners is not eligible for exemption; and research involving children has more restrictive exemption criteria* ***(see letter F below for additional details)***

Healthy adult students and instructors, ages 18 up to retirement age. The project has already involved over 200 instructors and over 25000 students. The maximum number of total participants may reach as many as 1000000.

D. Describe the consent process for enrolling subjects into this study including whether an oral or written consent process will be used

Participating students will access the online survey only after acknowledging (via an online survey format) they have read and understood the information and consent documentation provided. Instructors will agree to participate only after only after acknowledging (via an online survey format)they have read and understood the information and consent documentation provided. Information and consent information for 1) student participants and 2) instructor participants is included below. 1) Information and Consent for Student Participants Purpose and Investigator: The Transparency in Learning and Teaching Initiative is a study that aims to gather information about how higher education students understand their own learning processes and how instructors can enhance that understanding. Your responses will help institutions of higher education improve students' learning experiences. If you have questions at

any time about the study or your partic[illegible]tion in it, you may contact the study's p[illegible]cipal investigator, Dr. Mary-Ann Winkelmes, Coordinator of Campus Instructional Development and Research, Office of the Vice Provost for Faculty, Policy and Research, University of Nevada, Las Vegas (Mary-Ann.Winkelmes@unlv.edu, tel. 702-895-3455) mawink@illinois.edu. You may also contact the Office of Research Integrity %u2013 Human Subjects, University of Nevada, Las Vegas at 702-895-2794 or by email at IRB@unlv.edu for information about the rights of human subjects in approved research, identifying yourself as a research subject. Procedures, Dissemination and Confidentiality: You are selected and invited to participate in this study because your course instructor(s) agreed to participate in the study. You will be asked to take about 4 minutes to complete an online survey. No key or other identifier will link your answers with your identity. Your answers will always remain anonymous. Anonymous averages of the responses, only in aggregate form, will be shared with course instructors only after grades have been submitted to the registrar. The survey data will be stored on a secured server at the University of Illinois, accessible only through a password protected account on a password-protected computer, and also in a locked cabinet in Dr. Winkelmes's office. Data from the survey will be preserved for the duration of this ten-year study (2009-2019). Dr. Winkelmes and several collaborators will code and analyze data, interpret the findings, and disseminate the study's context, purpose, methods, findings, limitations, and conclusions through presentations and publications in higher education conferences, journals, and/or books. No individual names of Transparency Initiative participants will be identified in any reports, presentations, or publications. Benefits/Risks and Voluntary Participation: Your participation in this research is voluntary. Your decision to participate, decline, or withdraw from participation will have no impact on your grade in this course or on your present or future relations with your instructors or school or the University of Illinois at Urbana-Champaign in any way. There are no known risks from participation in this study beyond those that exist in normal daily life. There may not be immediate direct benefits to you as a participant. You may benefit from this project by becoming more aware of your own learning practices and how these impact your performance in school. You will be providing valuable information about your learning processes that will help schools and faculty to improve students' learning experiences. You may skip questions or terminate your participation at any time. I HAVE READ AND UNDERSTOOD THE INFORMATION ABOVE AND CONFIRM THE FOLLOWING STATEMENTS: I understand that my participation is entirely voluntary. I understand that I may refuse to participate or may discontinue participation at any time during the project without penalty, simply by closing my browser. I understand that I may skip any questions that I don't wish to answer. I understand that my anonymity will be preserved and my identity will never be connected with my responses. I am 18 years of age or older. I understand that the investigator will disseminate aggregate data from this survey in reports of this research at professional meetings and in professional publications, and that the names of participants will not be recorded or revealed. ---------- 2) Information and Consent for Instructor Participants Purpose and Investigator: The Transparency in Learning and Teaching Initiative is a study that aims to gather information about how higher education students understand their own learning processes and how instructors can enhance that understanding. Your responses will help institutions of higher education improve students' learning experiences. If you have questions at any time about the study or your participation in it, you may contact the study's principal investigator, Dr. Mary-Ann Winkelmes, Coordinator of Campus Instructional Development and Research, Office of the Vice Provost for Faculty, Policy and Research, University of Nevada, Las Vegas (Mary-Ann.Winkelmes@unlv.edu, tel. 702-895-3455) mawink@illinois.edu. You may also contact the Office of Research Integrity %u2013 Human Subjects, University of Nevada, Las Vegas at 702-895-2794 or by email at IRB@unlv.edu for information about the rights of human subjects in approved research, identifying yourself as a research subject. Procedures, Dissemination and Confidentiality: By clicking the %u201Csubmit%u201D button at the bottom of the online registration form, you indicate your voluntary participation in the Transparency Initiative. You will invite your students at the end of term to complete a 4-minute online survey located at a URL that will be provided to you, and at the end of term you will be asked how frequently (if at all) you chose to implement transparent modes of teaching and learning in your course. The investigators will keep your identity confidential. Your name will not be used in any presentations or publications resulting from the Transparency study, nor will it be shared with your institution%u2019s Review Board or other administrators. Your data will always remain anonymous and will be shared only in aggregate form. Your students%u2019 identities will never be recorded or tracked. Students%u2019 responses will always remain anonymous. Anonymous averages of students%u2019 responses, only in aggregate form, will be shared with course instructors only after grades have been submitted to the institution%u2019s registrar or equivalent. Data will be stored on a secured server at the University of Illinois, accessible only through a password protected account on a password protected computer, and also in a locked cabinet in Dr. Winkelmes%u2019s office. Data will be preserved for the duration of this ten-year study (2009-2019). Dr. Winkelmes and several collaborators will code and analyze data, interpret the findings, and disseminate the study%u2019s context, purpose, methods, findings, limitations, and conclusions through presentations and publications in higher education conferences, journals, and/or books. No individual names of Transparency Initiative

participants will be identified in a[illegible] reports, presentations, or publications. B[illegible]efits/Risks and Voluntary Participation: Your participation in this research is voluntary. Your decision to participate, decline, or withdraw from participation will have no impact on your present or future relations with the University of Illinois at Urbana-Champaign in any way. There are no known risks from participation in this study beyond those that exist in normal daily life. There may not be immediate direct benefits to you as a participant. You may benefit from this interview by becoming more aware of your own teaching practices and how these impact your students%u2019 learning. You may terminate your participation at any time. I HAVE READ AND UNDERSTOOD THE INFORMATION ABOVE AND CONFIRM THE FOLLOWING STATEMENTS: %u2022 I understand that my participation is entirely voluntary. %u2022 I understand that I may refuse to participate or may discontinue participation at any time during the project without penalty. %u2022 I understand that my confidentiality will be preserved by the investigators. %u2022 I understand that the investigator will disseminate aggregate data from this project in reports of this research at professional meetings and in professional publications, and that the names of participants will not be revealed. %u2022 I understand that by clicking the %u201Csubmit%u201D button at the bottom of the online registration form, I indicate my voluntary participation. Please print a copy of this consent form for your records.

D.1. If you are not obtaining consent, please provide your rationale ***(Otherwise enter N/A)***:

N/A

E. Describe how the data will be protected ***(include location, length of time and disposition of data)***.

Data from online surveys will be stored on a password protected computer in a locked office and on a backup drive kept in a locked drawer in the locked office of the principal investigator. Students' anonymity will be preserved. Students' identities will never be tracked: no key or other identifier will link students' answers with their identity. Data from the survey will be preserved for the duration of this five-year study (2013-2018). Instructors' identities will be known only to the principal investigator, who will keep these identities confidential. Instructors' names will not be used in any reports, presentations or publications resulting from the Transparency Initiative, nor will identities be shared with their institutions%u2019 Review Boards or other administrators. Instructors' data will be shared only anonymously in aggregate form.

F. If you will be using a questionnaire, survey or interview procedure, please indicate the setting where the research will take place ***(NOTE: Interview or survey research involving children cannot be exempt from IRB review.)***:

- ☐ No questionnaire, survey or interview procedures used
- ☐ Classroom
- ☐ UNLV
- ☐ Subjects' home ***(e.g., mailed survey)***
- ☑ Electronic/internet forum
- ☐ Other, please specify:

## 11. Category 4 Details ***(This section is to be completed if you selected Category #4 in Section 5 above - and Category #4 is marked FALSE)***

11.1 If you selected category 4 in section 8 above and your project involves the collection of data ***(e.g., medical records/chart review/academic records/database research), answer the following:***

*Note: If you are recording identifiable information from medical records, charts, academic records, or recording the medical record number or code linking information to the medical/academic record number, the project cannot be exempted under the federal regulations. A Protocol Proposal Form must be submitted for such studies.*

a) Identify the source of the data

b) Provide the date range of the data to be collected. Include specific dates and state whether the data will be in existence at the time you submit this application to the IRB:

c) Provide the estimated number of subjects whose data will be collected for the study:

d) Indicate how the study data will be recorded so that it is not identifiable ***(e.g. study data will not include direct identifiers or a code linking data to subjects' identity)***:

e) Indicate who will access the medical records and how they have valid clinical access to these records (e.g., involved in the patients' care). Valid clinical access is defined as individual normally having access to the records as part of their usual clinical activities):

f) Attach a copy of the data collection sheet that details the data that will be collected for this project. If you are not attaching, please check here: ☐

If a data collection sheet is not being attached to this application, please explain why:

## 12. Financial Information

12.1 Will subjects be paid or otherwise compensated for research participation? ○ Yes ◉ No

*If yes, please respond to the following questions:*

a) Describe the nature of any compensation to subjects. Include cash, gifts, research credit, etc.

b) Provide a dollar amount, ***(if not applicable, check here: ☐)***, if applicable $ , and indicate method of payment

☐ Cash ☐ Check ☐ Research Credit ☐ Other Payment:

c) When and how is the cash compensation provided to the subject?

d) What is the effect on cash compensation if a subject does not complete the study?

12.2 Is there any internal or external funding ***(e.g., grants, contracts, gifts, etc.)*** ○ Yes ◉ No

*If yes:*

a) Name of Sponsor or UNLV Grant Program:

b) Attach a copy of the proposal and/or award document through the Supporting Documents Grid from the Home Page of CyberIRB.

## 13. Protected Health Information (PHI)

All projects must indicate whether PHI will be used and/or disclosed as part of the research. Please select ONE of the following:

☑ The activity is EXEMPT from research HIPAA requirements as no PHI is used or collected ***(Information collected must have all 18 elements as defined by the HIPAA Privacy Rule removed so that an individual or the individual's relatives may not be identified)***

☐ A waiver for use and/or disclosure of PHI is requested ***(submit a request for waiver of HIPAA Authorization)***

☐ HIPAA Authorization for use and disclosure of PHI will be obtained from subjects ***(submit a HIPAA Authorization form)***

☐ A limited data set will be ut[illegible]ed *(The only identifying elements from the list of [illegible]AA identifiers that may be included are city, state, and/or ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers)*

*Please note: A Data Use Agreement (DUA) is required to use and/or disclose information contained in a "limited data set". Please provide a copy of the executed DUA along with this submission. Submissions cannot be processed without this document.*

## 14. 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 OPRS 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 OPRS 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 checking this box*** ☑ ***and submitting this form electronically, I agree to the assurance as stated above.***

Please ensure your Supporting Documents have been added through the Protocol Summary Page (button on the left), and send your protocol by clicking the Send button from your Home Page.