Interdisciplinary Ed.D. Program in Leadership

CITI/IRB Manual

This manual is not intended for the Superintendent Track students. Superintendent Track students need to contact Dr. Barbara Brock at barbarabrock@creighton.edu

Updated November 20, 2012

Creighton University
2500 California Plaza
Omaha, NE 68178

Contents

IRB BASIC SOCIAL BEHAVIORAL

The current requirements for IRB Certification are the completion of 3 online courses for the protection of human subjects in research, the CITI Basic Social Behavioral course, the CITI Social Behavioral Responsible Conduct of Research (www.citiprogram.org), and the submission of 2 acknowledgements, one for the IRB's Policies and Procedures which can be found on the website (IRB Policies and Procedures), and the second for the Creighton University's Research and Sponsored Programs Compliance Plan which is also found on our website (Research Compliance Plan). In addition, everyone must also complete the CITI Conflict of Interest Mini Course and submit an annual Financial Conflict of Interest Disclosure (FCOI). If you will be participating in any project which receives funds from NIH, you are required to complete a short NIH FCOI tutorial. The instructions for accessing the CITI website and getting started with the all the CITI courses can be found on page 4.

The Acknowledgements may be completed online and emailed to me (MaryRitterbush@creighton.edu). The Financial Conflict of Interest Disclosure once completed needs to be returned to Sara Coolman, at saracoolman@creighton.edu. All forms can be found on pages 6-10.

If there are any questions or problems, please contact me. I am usually in the office between 7:30 am and 4:30 pm, Monday through Friday. After normal business hours I can be reached on my cell phone at 402-740-0341, or by email. Please let me know if there is anything else you need regarding this process.

Mary Ritterbush
Research Compliance Education Coordinator
Creighton University
Criss I, Room 123
2500 California Plaza
Omaha, Ne 68178
402.280.2680. (office)
402.740.0341 (cell)
402.280.4766 (fax)

CITI/IRB Certification Checklist

Complete the following three courses: Date

- Basic Social Behavioral Course (19 modules) _____
- Responsible Code of Research Course (17 modules) _____
- Conflict of Interest Course (5 modules) _____

Complete the following forms:

- Disclosure of Financial Relationship for Sponsored Projects (send to COI@creighton.edu) _____
- Acknowledgement of the Research and Sponsored Programs Compliance Plan (send to MaryRitterbush@creighton.edu) _____
- Investigator(s) and/or Research Personnel Acknowledgment of Access to the IRB's Policies and Procedures (send to MaryRittebush@creighton.edu) _____

Received 3 Certificates from IRB (Examples on page 11) _____

***Please take note, the 3 certificates are not the completion reports that you can print at the end of each course. The Certificates will be sent to you by our IRB Office. (see example on page 25)*

Send copies of the 3 certificates to the Ed.D. Office to ckarasek@creighton.edu _____

Completing the Collaborative Institutional Training Initiative (CITI) IRB courses is one of three criteria needed for Initial Certification by the **Creighton University Institutional Review Board for the Human Subjects Research Education Program.**

Course Description

Basic Social Behavioral and Responsible Conduct of Research Courses

- CITI is a web-based tutorial maintained by the University of Miami.
- The courses have been developed by experts in the human subject's safety community. Each course consists of modules most modules have an associated quiz.
- The first course, "Basic Social Behavioral Course", consists of 19 modules that are required of *all* investigators, staff, and students performing Social Behavioral Research
- The second course is the Responsible Conduct of Research, which consists of 17 modules. You will select the Social Behavioral Responsible Conduct of Research course.
- For Recertification, investigators, staff, and students need to complete *all* of the modules listed in the "Refresher Course" that correlates with initial certification. Investigators, staff, and students will be notified by CITI when recertification is required (recertification is required every 3 years).
- Theses course will requires about 4-6 hours to complete — investigators, staff, and students DO NOT have to complete the entire course in one session. The site may be visited as many times as necessary.

Conflict of Interest Mini Course

- CITI is a web-based tutorial maintained by the University of Miami.
- The COI Mini-Course consists of 5 modules and required for all Investigators/Support Personnel. The modules are:
    - Introduction to Conflict of Interest
    - Financial Conflict of Interest: Overview, Investigator Responsibilities, and COI Rules
    - Institutional Responsibilities as They Affect Investigators
    - Conflict of Interest Institution-Specific Policies
    - Conflict of Commitment, Conscience, and Institutional Conflicts of Interest
- **IF THIS IS THE FIRST TIME TAKING THE CITI WEB-BASED COURSE, AN INVESTIGATOR, STAFF MEMBER OR STUDENT MUST TAKE THE BASIC COURSE. DO NOT TAKE THE REFRESHER COURSE!!!**

How to Access the Course — Getting Registered

- Go to the CITI Registration website at http://www.citiprogram.org/, and select **New User Register Here** if the first time. Follow the directions.
- You will first, select the *Participating Institution*. **It is very important that you select Creighton University.** (CITI will use this selection to notify us once you have completed a course.) Second, you will select your User ID and password. **Please retain your username and password for your records. Investigators, staff and students will use the same username and password each time you log onto the CITI website.** Next you will

be asked to provide CITI with some general information (name, e-mail address, department, etc)

- **Please retain your username and password for your records. Investigators, staff, and students will use the same one each time you log on to the CITI web-site.**
- **NEXT,** you will need to make four selections. **The first selection,** for question 1 on the page titled "Select Curriculum" you will need to select a Group –Group 2 for **Social Behavioral**.
- **The second selection,** question 2. **IF THIS IS THE FIRST TIME YOU ARE TAKING THE CITI ON-LINE COURSE, YOU MUST CHOOSE THE LAST OPTION – "I have not previously completed an approved Basic Course."**
- Skip question 3!
- **For the third selection,** scroll down to question 4, **Responsible Conduct of Research.** Please select the area that best describes your area of research. **ONLY SELECT ONE (1) COURSE, Social Behavioral!!**
- **Finally,** scroll down to question 8, **Conflict of Interest Mini Course.** Please select the "Yes" option.
- If you are renewing your IRB certification, you will need to take the **Continuing Education Course**, rather than the Basic. Question 2 is where you will indicate which course you will be taking.
- After you make your selection, scroll down to the bottom of the page and hit the "select" button.

Completing the Course

- Find the name of the course under "My Courses" on the Main Menu page. To the right of the course name in red you will see Not Started – Enter. Click on the word Enter.
- You will see the list of modules to complete - click on the Introduction module to begin.
- You do not need to complete all of the modules at once.
- Follow the directions as you proceed through the course.
- You must complete the exam with a minimum score of 80% for certification.

When You Are Finished

- **ALL REQUIRED COURSES MUST BE COMPLETED** in order to receive credit for Initial Certification or Recertification. **Please print a copy of the Completion Reports for your records.** A copy of your completion report will by sent by CITI to the Research Compliance Education Coordinator (Institutional Administrator). You should retain a copy of your completion report in the event that the Research Compliance Office does not receive a copy from CITI.
- You will receive IRB Certification after all requirements (including CITI) of the Creighton University Human Subjects Research Education Program have been fulfilled. If you believe you have completed all the requirements for IRB Certification, but have not received your Certificate, please contact Mary Ritterbush at 280-2680 or maryritterbush@creighton.edu
- For those requiring Continuing Education you will receive IRB Recertification after the Refresher Course for CITI has been completed.

Contact

- Please contact the Research Compliance Education Coordinator, Mary Ritterbush at 280-2680 or
- maryritterbush@creighton.edu, with questions.

Creighton UNIVERSITY

Creighton University Research and Compliance
2500 California Plaza, Omaha, NE 68178 • Phone: 402-280-3074
Fax: 402-280-4766 • http://www2.creighton.edu/researchcompliance/

DISCLOSURE OF FINANCIAL RELATIONSHIP FOR SPONSORED PROJECTS (08/24/2012—8/23/2013)

Name (Print): _____ Date: _____
Department: _____ Phone: _____
E-mail Address: _____

Please check appropriate boxes:

☐ Initial Disclosure	☐ Annual Disclosure	☐ Update
☐ Investigator	☐ Co-Investigator	☐ Support Personnel
☐ Committee Member	☐ PHS-funded	☐ Student

This Form shall be completed by all Investigators/Support Personnel/Research Committee Members pursuant to University Policy 3.1.10, Financial Conflict of Interest in Research.

Section A. Financial Interests/Relationships

Report all financial interests/relationships currently held, or held within the past 12 months (or during the previous calendar year for annual disclosures), unless otherwise stated, indicating the amount of the financial interest/relationship and the entity or organization. This form must be updated with 30 days of acquiring any new or additional financial interests/relationships.

1. For Publicly Traded Entities: Payment for Services (Remuneration) and/or Equity (Ownership) Interests. Have you and/or your spouse or dependents received or will you and/or your spouse or dependents receive any salaries and/or other payments (e.g., consulting fees; honoraria, study design; management position, independent contractor, service on advisory committees or review panels of for-profit entities, board membership of for-profit entities; seminars, lectures or teaching engagements for for-profit entities; any interest that could be affected by the outcome of the research) from any one entity or group of related entities, or do you and/or your spouse or dependents hold any equity interests or ownership interest (e.g., stock, stock options, partnership) that when totaled together for any entity or group of related entities exceeded **$5,000** in value during the previous 12 months or that currently as of the date of this disclosure exceed **$5,000**? **NOTE:** Equity interests exclude interests in diversified mutual funds, unless you or your spouse/dependents have the ability to directly control the direction of the investments.

☐ Yes ☐ No

If Yes, note exact amount with explanation of source(s):

_____
_____

2. For Non-publicly Traded Entities: Payment for Services (Remuneration). Have you and/or your spouse or dependents received or will you and/or your spouse or dependents receive any salaries and/or other payments (e.g., consulting fees; honoraria, study design; management position, independent contractor, service on advisory committees or review panels of for-profit entities, board membership of for-profit entities; seminars, lectures or teaching engagements for for-profit entities; any interest that could be affected by the outcome of the research) from any one entity or group of related entities, that when totaled together for any entity or group of related entities exceeded $5,000 in value during the previous 12 months or that currently as of the date of this disclosure exceed **$5,000**?

☐ Yes ☐ No

If Yes, note exact amount with explanation of source(s):

_____
_____

3. For Non-publicly Traded Entities: Equity (Ownership) Interests. Do you and/or your spouse or dependents hold any equity interests or ownership interests (e.g., stock, stock options, partnership) in non-publicly traded entities? **NOTE:** The threshold for equity (ownership) interests is **$0**; you must report all such interests here. **NOTE:** Equity interests exclude interests in diversified mutual funds, unless you or your spouse/dependents have the ability to directly control the direction of the investments.

☐ Yes ☐ No

If Yes, note exact amount with explanation of source(s):

_____

_____

4. Reimbursed Travel (for Investigators/Support Personnel involved in PHS-funded projects): Have you and/or your spouse or dependents received or will you and/or your spouse or dependents receive any reimbursement for travel and related expenses (e.g., transportation, lodging, meals, incidentals) that are related to your institutional (professional) responsibilities? **NOTE:** This does not include travel that is reimbursed by a Federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institution that is affiliated with an institution of higher education.

☐ Yes ☐ No

If Yes, note the following:

The purpose of the trip: _____

The identity of the sponsor/organizer: _____

The destination of the travel: _____

The duration of the travel: _____

The monetary value of the travel: _____

5. Sponsored Travel (for Investigators/Support Personnel involved in PHS-funded projects): Have you and/or your spouse or dependents received or will you and/or your spouse or dependents had any travel and related expenses (e.g., transportation, lodging, meals, incidentals) paid on your behalf (i.e., are not reimbursed) that are related to your institutional (professional) responsibilities? **NOTE:** This does not include travel that is sponsored by a Federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institution that is affiliated with an institution of higher education.

☐ Yes ☐ No

If Yes, note the following:

The purpose of the trip: _____

The identity of the sponsor/organizer: _____

The destination of the travel: _____

The duration of the travel: _____

The monetary value of the travel: _____

6. Contingent Compensation. Have you and/or your spouse or dependents received or will you and/or your spouse or dependents receive any compensation that will be contingent on the outcome of the research?

☐ Yes ☐ No

If Yes, note exact amount with explanation of source:

_____

_____

7. Other Financial Interests or Relationships. Have you and/or your spouse or dependents received any loans, payments, gifts, in-kind contributions or similar financial interests or relationships that are in any way related to your institutional (professional) responsibilities?

☐ Yes ☐ No

If Yes, note exact amount with explanation of source:

_____

_____

8. Incentives. If involved in any research activity, will you receive any money, gift, or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, an enrollment bonus for reaching an accrual goal or similar types of payments?

☐ Yes ☐ No

If Yes, note exact amount with explanation of source:

_____

_____

9. Intellectual Property or Proprietary Interests. Do you and/or your spouse or dependents have any intellectual property or proprietary interests related to your institutional (professional) responsibilities, including, but not limited to, a patent, trademark, copyright, licensing agreement, or royalties, licensing fees, or other monies related to the intellectual property or proprietary interest not paid through the University?

☐ Yes ☐ No

If Yes, note exact amount with explanation of source:

_____

_____

10. Other. Do you and/or your spouse or dependents have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

☐ Yes ☐ No

If Yes, note exact amount with explanation of source:

_____

_____

Section B. Attestation

I affirm that I:

Have read the University Policy 3.1.10, Financial Conflict of Interest in Research, and agree to abide by its terms.

Will update this Disclosure Form on an annual basis or as any new reportable significant financial interest arises.

Will comply with any resolution plan proposed by the CIRC (and/or IRB, if the project involves human subjects) to manage, reduce or eliminate any actual or potential financial conflict of interest before conducting any research where a conflict of interest has been identified by the CIRC.

Understand that, if I am a PHS-funded Investigator/Support Personnel, information on all financial conflicts of interest will be made publicly accessible.

Understand and agree that if I submit this electronically with a typed signature, this will be considered my legally binding signature.

Signed: _____ Dated: _____

➢ **Submit the completed form and send a signed PDF copy OR a copy with a typed signature via email to**

COI@creighton.edu

OR mail a signed paper copy to:

Sara Coolman, Associate Director for Research and Compliance
Research Compliance Office, CRISS I, Room 109

ACKNOWLEDGEMENT OF THE RESEARCH AND SPONSORED PROGRAMS COMPLIANCE PLAN

I acknowledge that I:

1. Have access to the **Creighton University** ***Research and Sponsored Programs Compliance Plan*** available on the website: www.creighton.edu/researchcompliance/rcc/complianceplan, and I agree to read the Plan.
2. Will comply fully with the standards contained in the Plan and any other compliance policies/procedures applicable with my responsibilities to Creighton University.
3. Will report any conduct that I believe to be illegal or to violate the Plan or any research compliance policy/procedures to my supervisor or the Research Compliance Officer (402-280-2360) or the University Research Compliance Hotline (402-280-3200).
4. Will seek advice from my supervisor or the Research Compliance Officer regarding any actions required to comply with the Plan or any research compliance policy/procedure.
5. Understand that this Plan does not, in any way, constitute an employment contract or an assurance of continued employment.

The Creighton University Research Compliance Committee reserves the right to occasionally amend, modify, or update this Manual.

Understand and agree that if I submit this electronically with a typed signature, this will be considered my legally binding signature.

Name Printed	Signature
Department	Position
Office Phone	Email
Date	

☐Faculty ☐Staff ☐Student ☐Other

➢ **Submit the completed form and send a signed PDF copy OR a copy with a typed signature via email to**

MaryRitterbush@creighton.edu

INVESTIGATOR(S) AND/OR RESEARCH PERSONNEL ACKNOWLEDGEMENT OF ACCESS TO THE IRB'S POLICIES AND PROCEDURES

I acknowledge that I:

Have access to the **Creighton University IRB's *Policies and Procedures for the Use of Human Subjects in Research*** available on the website: IRB Policies and Procedures, and I agree to read the policies and procedures, containing the following information:

Creighton University Institutional Review Board Policies and Procedures
Creighton University Federalwide Assurance
Nuremberg Code
Declaration of Helsinki
Belmont Report
Food and Drug Administration, Title 21 CFR Part 50
Food and Drug Administration, Title 21 CFR Part 56
Department of Health and Human Services, Title 45 CFR Part 46
Federal Regulations Comparison Table
Web Site Resources

6. Will comply fully with the standards contained in the *IRB's Policies and Procedures for the Use of Human Subjects in Research* and any compliance policies and procedures applicable to my responsibilities to Creighton University.
7. Will report any conduct that I believe to be illegal or to violate the IRB Policies and Procedures or any research compliance policies and procedures to the Associate Vice President for Research and Compliance (280-2360) or the Research Compliance Hotline (280-3200).
8. Will seek advice from the Associate Vice President for Research and Compliance regarding any actions required to comply with the IRB Policies and Procedures or any research compliance policies and procedures.
9. Understand that this Manual does not, in any way, constitute an employment contract or an assurance of continued employment.

Creighton University's Institutional Review Board reserves the right to occasionally amend, modify, or update these Policies and Procedures.

Name Printed	Signature
Department	Position
Office Phone	Email
Date	

☐Faculty ☐Staff ☐Student ☐Other

➢ **Submit the completed form and send a signed PDF copy <u>OR</u> a copy with a typed signature via email to**

MaryRitterbush@creighton.edu

IRB Project Approval

http://www.creighton.edu/researchcompliance/institutionalreviewboards/policiesandprocedures/index.php

a. A students project will need to be approved by answering the following questions:
   - Is the proposed activity research? Research Definition: research is a systematic investigation that includes research development, testing, and evaluation and is designed to develop or contribute to generalize knowledge. If answer is NO, IRB is not required.
   - Does it involve human subjects? Human Subject definition: Living individual about whom an Investigator (whether professional or student) conducting research obtain 1) data through intervention or interaction with the individual, or 2) identifiable private information. Consult with the IRB office for assistance. If answer is NO, IRB is not required.
   - Will it be authorized and conducted under the jurisdiction of Creighton University?

b. What type of Review is required
   - **Exempt Status review**: Use of human subjects in entirely noninvasive actives, such as educational surveys that involve subjects 19 years and older, do not include vulnerable subjects and is minimal to no risks.
   - **Expedited review**: use of human subjects in minimally invasive procedures involving minor risk
   - **IRB Convened Meeting:** Includes all prisoner research. Research involving children shall not be exempt for those projects that require observation only or record review. All studies involving greater than minimal risk and vulnerable populations.

c. Submission Requirements
   - Submit application for "Initial IRB Review (Social-Behavioral)
   - Submit hard copy to IRB Office, Criss I, room 104. If expedited also submit an electronic copy to irb@creighton.edu as well.
   - Submit project for approval before you can begin work
   - Student investigators must be listed as Student-Investigators.
   - The students advisor will be Principal Investigator
   - Submit protocol or study design, including the purpose of the research, the scientific or scholarly rationale, procedures to be performed, a description of the procedures being performed already for diagnostic or treatment purposes, the risks and potential benefits of the research to participants, and a list of references. (Template can be found under Policies and Procedures on IRB website 108.3)
   - Any necessary application attachments
   - Full grant applications
   - Informed consent document (template with required elements on IRB website)
   - Information script (for projects that have documentation of consent waived)
   - Assent document(s) (age 7-11, age 12-18)
   - Parental permission document
   - Genetic testing consent documents
   - HIPAA authorization
   - Questionnaires/surveys
   - Interview questions

- Investigator's brochure
- Recruitment materials
- Any documents that will be given or seen to research subjects
- Previously reviewed projects by a local IRB other than Creighton IRB, please provide copy of the approval or disapproval letter from that IRB
- A copy of any documents or items given to subjects such as diary cards, small gifts, etc.
- If the project is done at a site not affiliated with Creighton University and the site does not have an IRB; a letter of agreement from the cooperative organization is needed.
- For projects that require review at a convened meeting, please submit full packet with required copies. If full packet is not submitted, it may result in a 4 week delay. The schedule of meetings and corresponding submission deadlines may also be found on the IRB website.

**If the project is expedited or full board CITI training, conflict of interest disclosures (only if funded) are required before any research project is approved. Contact Mary Ritterbush, the Education Coordinator, at 402-280-2680 or MaryRitterbush@creighton.edu.*

Creighton University
Creighton University Institutional Review Board
2500 California Plaza, Omaha, NE 68178 • Phone: 402-280-3074 • Fax: 402-280-4766
http://www.creighton.edu/researchcompliance/institutionalreviewboards/about/index.php

Application for

Initial IRB Review Social-Behavioral: IRB-02

IRB #:

Please email the EXACT title of the protocol and the name of the Principal Investigator to irb@creighton.edu and an IRB number will be generated from the IRB database.

Check appropriate box for type of review:
☐ Convened Meeting (Full Board)
☐ Expedited Review (On Attachment A, check the category that would allow this type of review, and attach to this application)

For Office Use Only
Date and Time of Convened Meeting: _____

1. Contact and Study Information

All study personnel must complete the mandatory Creighton University Human Subjects Research Education Program prior to approval of this study. For all personnel listed, please indicate whether this requirement has been met by checking yes under "Protection of Human Subject Certification current."

Certification **MUST** be renewed every three years. If you have any questions regarding education requirements, please visit the Education and Training web page or call the Research Education Coordinator at 402-280-2680.

Study Title: (Please list title **exactly** as it appears on the protocol and consent documents)			
Principal Investigator (include degree/credentials):		Protection of Human Subject Certification current ☐ Yes ☐ No	
Phone:		E-mail:	
Department & School:			
Person(s) Responsible for Regulatory Documents:	☐ Same as PI or		
Phone:		E-mail:	

Study Responsibilities

1	Obtain Informed Consent*	6	Perform study-related activities with participants (including observation)*
2	Make subject eligibility/enrollment decisions*	7	Submit and maintain IRB approvals and renewals
3	Data collection	8	Maintain documentation for Investigator Site File
4	Data entry	9	Other (please specify)
5	Data analysis	10	Community Partner (for Community-Based Participatory Research)**
* Requires Protection of Human Subject Certification ** For training requirements, see IRB Policy 133, "Community-Based Research"			

Investigator/Study Personnel Name (include degree/credentials)	Role in the Study (Investigator, Data Entry, Technician, Student Investigator)	Responsibilities	Protection of Human Subject Certification current
Please note: if study personnel will be involved in the consent process, they must be listed as an investigator on the consent/permission/assent documents.			
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A
			☐ Yes ☐ N/A

- All Personnel who are not Creighton University, Missouri Valley Cancer Consortium, or Alegent Health personnel must provide with this application a curriculum vitae and certificate of training for the Protection of Human Subjects, if certified outside of Creighton University.

2. Project Sites

This project is being conducted at the following Creighton sites or Creighton-affiliated sites:

☐ Creighton University (including ambulatory centers)
☐ Creighton University Medical Center/St. Joseph Hospital (patient is admitted as inpatient or outpatient) IF CHECKED, PLEASE COMPLETE COST SHEET. CALL: 402-449-4297 and submit the research committee signed cost sheet or email approval.
☐ Alegent Health Facilities: IF CHECKED, please submit the Scientific Review form that verifies approval from Alegent Health Research Committee. CALL: 402-715-4757 ☐ Boystown National Research Hospital: If CHECKED, please submit proof of permission from the BTNRH officials. CALL: 402-498-6325 ☐ Missouri Valley Cancer Consortium ☐ The Creighton University PI is the lead researcher of a multi-site study or provides study-wide services, such as data coordination. List sites for which the PI has responsibility:
☐ Other (please specify): If the study is being conducted at a non-Creighton affiliated site that does not have IRB oversight, an agreement between that site and the Creighton IRB must be completed prior to starting the project. (See the letter of agreement template)

For multi-institution projects for which Creighton University is the lead institution: This project is being conducted at the following subcontracted sites that provide their own IRB oversight for the project:

☐ Institution name and location:	
☐ Institution name and location:	
☐ Institution name and location:	
If the study is being conducted at a subcontracted site that provides its own IRB oversight, the Creighton University IRB office must obtain an agreement between that site and Creighton University prior to starting the project. Contact the IRB office at 280-3586 for more information.	

3. Project Sponsorship Information

Will this project receive external funding? ☐ Yes ☐ No

If yes, please list the funding agency

☐ Is the research to be funded by the U.S. Department of Defense? ☐ Yes ☐ No

If yes, see IRB Policy 126, "Additional Department of Defense Requirements."

☐ Is the research to be conducted at a school funded by the U.S. Department of Education or is the research directly funded by the U.S. Department of Education? ☐ Yes ☐ No

If yes, see IRB Policy 116, "Vulnerable Research Populations," Section 3, for information about complying with the Protection of Pupil Rights Amendment, and IRB Policy 118, "Informed Consent (Including Permission/Assent)," Section 6.1.4, for information about complying with the Family Educational Rights and Privacy Act (FERPA).

Is the research being done at an Alegent site by someone affiliated with Alegent Healthcare? (Fees negotiated per contract with Creighton University.) ☐ **Yes** ☐ **No**

When studies are funded by an external source, the University is required to have financial disclosures on file with the Research and Compliance Office.

4. Conflict of Interest

If this study is funded by any outside source complete this section:

Do any investigators have a financial relationship with the sponsor of this research?	☐ Yes (CIRC review required)	☐ No
If yes, which investigator has the conflict? Name of agency with which the conflict exists:		
Have all investigators listed submitted an annual disclosure?	☐ Yes	☐ No (If this study is funded, these must be submitted prior to approval)
Has any investigator had a change to there financial interests in which they have not yet disclosed?	☐ Yes (The disclosure must be updated)	☐ No

5. Scientific Review (All projects are required to have a scientific review if they require review at convened meeting (must check one))

☐ This project had a formal scientific review (e.g., NIH). By whom _____

☐ This project had an internal scientific review (e.g., Form 108.1 is attached). An internal peer review from appropriate disciplinary and content expert(s) is required before the project can be reviewed by the IRB. (See IRB Policy 108, "Scientific/Methodological Review of Investigator-Initiated Research")

☐ Project presents no more than minimal risk, but a scientific review was performed (attach a copy of the review to this application).
☐ Project presents no more than minimal risk and additional peer review was not performed. All studies, regardless of risk, conducted at Alegent Health require scientific review through the Alegent Health research committees.

6. **Risk Category (to be provided by the PI)—**Identify the perceived risk to human participants expected to participate in the research project, including your rationale for the level of risk identified.

a. Research involving **adults** (check perceived risk)
☐ Minimal risk (risks no greater than one would encounter in daily life). **If this project could be considered to be reviewed using the expedited procedure, complete and attach Form A.**
Rationale:
☐ Greater than minimal risk
Rationale:
Describe the plan to minimize risks:

b. Research involving **children** <19 years of age; including neonates
Please complete Attachment B and attach to this application

c. Research involving **pregnant women or fetuses**
Please complete Attachment C and attach to this application

d. Research involving **prisoners**
Please complete Attachment D and attach to this application

e. Research involving **adults with diminished decision-making capacity**
Please complete Attachment E and attach to this application

7. **Privacy**—Describe the procedures you will use to respect and protect the participant's privacy (physically, behaviorally, or intellectually) while in the study. (Privacy refers to persons and their interest in controlling the extent, timing, and circumstances of sharing themselves (physically, behaviorally, or intellectually) with others.)

_____

Describe the time and location where participants will give information.

_____

Describe who will be present during study visits and what information will be given during these visits.

_____

8. **Confidentiality (Data Collection)**

Will your data have human subject identifiers such as name, Social Security number, date of birth, student number, or any identifier that could link the data to a specific individual? ☐ Yes ☐ No
If yes, is the information considered Protected Health Information (PHI)? ☐ Yes ☐ No
If yes, a separate HIPAA authorization is required.

If no, will the anonymized data be gathered via:

☐ Creighton University Blue Q (IP tracking must be disabled when preparing the survey)

☐ Email correspondence

☐ Companies such as Survey Monkey (IP tracking must be disabled when preparing the survey)

☐ Paper data collection only

If anonymized data only, skip the rest of this section and go to Question 9.

If yes, will the identifiers remain on the study data when placed in permanent storage?
☐ Yes ☐ No

Who has access to identifiable data? (please select all that apply)
☐ The Principal Investigator
☐ The Creighton research staff listed in this application
☐ Other members of this study (outside of Creighton) specify
☐ Others not categorized above specify _____

Maintenance of Active Identifiable Data

Where do you maintain your paper files while the project is active?
☐ Creighton University Office
☐ Other, list

If, maintaining data electronically, where will the data be stored while the study is active? (please select all that apply)
☐ On a network server in a Creighton University Office (such as albatross)
☐ On the computer in my office
☐ On a laptop
☐ Other, specify _____

How is electronic data protected?
☐ Password-protected
☐ Encrypted computer
☐ Don't know (Contact the Computer Security Officer)
☐ Other _____

If using electronic files who maintains the computer(s) ?
☐ DoIT (campus services)
☐ Other, specify name of person _____

Storage of Identifiable Data After the Project is Completed

Where do you store your paper files when the project is completed?
☐ Creighton University Office
☐ Creighton University contracted storage vendor

☐ Other, list
☐ Do not store paper data; paper data converted electronically and destroyed

Complete if storing data electronically, where will the data be stored when the study is complete? (please select all that apply)
☐ On a server in a Creighton University Office
☐ On the computer in my office
☐ On a laptop
☐ On a sponsor database (outside of the university)
☐ Other, Specify _____

If stored electronically, how is electronic data protected?
☐ Password-protected
☐ Encrypted computer
☐ Don't know
☐ Other _____

Is data from your study transmitted, in **any** fashion, outside of the University (i.e. paper, email, FTP, USB flash drives, US Postal Service, courier, etc)?
☐ If yes, describe _____
☐ No

How long will you store this data after study complete?
☐ Minimum required by University policy (3 years and 3 months after study closed)
☐ As per contract; state # of years _____
☐ As per funding agency's requirement # of years _____
☐ Indefinitely
(See University Policy "Retention of University Research and Compliance Records"

9. Consent/Permission/Assent Process—Per Creighton University policy, only investigators are allowed to participate in the consent process. Investigators must be listed on the consent form and/or on page 2 of this application. See IRB Policy 118, "Informed Consent (Including Permission/Assent)."

Describe your consent/assent process, including waiting periods, mailings, need for interpreters/translators, etc.

_____

Who will provide consent/permission (e.g., participant, participant's legally authorized representative, participant's surrogate, parent/guardian of participant)?

_____

Describe how you will minimize coercion or undue influence over participants (e.g., enrolling students, employees, any person with whom any investigator on the project has a personal relationship). See IRB Policy 116, "Vulnerable Research Populations."

_____

Are you requesting a waiver of documentation of consent OR a waiver of consent? ☐ Yes ☐ No

(If yes, complete Attachment G and attach to this application)

10. Recruitment Process

a) What is the age range of participants? _____

b) Is there a potential to enroll adults who have diminished decision-making capacity (e.g., cognitive disabilities, severe mental illness, comatose or severely traumatized)?

☐ Yes ☐ No

If yes, please justify: _____

c) How many participants will be enrolled at this site? _____

d) If a multi-center project, how many participants will be enrolled at all sites? _____

e) Will any of the following populations be enrolled?

☐ Children (<19 years of age per State of Nebraska Law)

☐ Pregnant women, fetuses, or neonates

☐ Adults who have diminished decision-making capacity (e.g., cognitive disabilities, severe mental illness, comatose or severely traumatized)

☐ Prisoners (Please note that all research involving prisoners must be reviewed at a convened meeting)

f) Will any of the following vulnerable populations be **TARGETED** for this research?

☐ Employees	☐ Students	☐ Healthy volunteers
☐ Cognitive disabilities	☐ Severe mental illness	
☐ Racial and ethnic minorities	☐ Rural and urban poor	☐ Undocumented immigrants
☐ People with disabilities or multiple chronic conditions	☐ Members of Native American Tribes (must also submit Tribal approval)	☐ Any person with whom any investigator on the project has a personal relationship
☐ Patient with whom any investigator on the project has had a clinical relationship during the past 5 years		

If you are recruiting any of the above vulnerable populations, describe how the selection of participants is equitable in relation to the research, and describe outreach programs:

_____

g) Describe how you will minimize coercion or undue influence over participants.

_____

h) Describe your recruitment process for all populations: (Standard of practice allows a maximum of 3 attempts to directly contact potential participants. If you will make more attempts, please justify in your description.)

☐ Internal recruitment only. Describe: _____
☐ External recruitment (e.g., radio, TV, Internet, telephone). Describe: _____
☐ Recruitment of current patients. Describe: _____

You are encouraged to post all opportunities for participation in research to the Creighton University Research Participant Information web site. A separate electronic submission is required.

11. Compensation—If a stipend is to be paid, please describe amount and distribution of the stipend during the study: _____

12. Submission Requirements

☐ If submitted for review at a convened meeting, submit an original and seven (7) double-sided copies of the following to the Social-Behavioral IRB, and send an electronic copy of all documents, including protocols, consents, permissions, assents, HIPAA authorizations, and other documents submitted in the paper form, to the IRB office at irb@creighton.edu. Identify the documents with the assigned IRB number.

OR

☐ If submitted for expedited review, submit one original copy and an electronic copy of all documents, including protocols, consents, permissions, assents, HIPAA authorizations, and other documents submitted in the paper form, to the IRB office at irb@creighton.edu. Identify the documents with the assigned IRB number.

☐ Completed Application for Initial IRB Review
☐ Attachment A, Expedited Review
☐ Attachment B, Research Involving Children

☐ Attachment C, Research Involving Pregnant Women or Fetuses
☐ Attachment D, Research Involving Prisoners
☐ Attachment E, Research Involving Adults with Diminished Decision-making Capacity
☐ Attachment G, Waiver of Consent or Documentation of Consent
☐ Informed consent document (see consent checklist to ensure all elements of consent are included) or Information Letter (if consent documentation is waived)
☐ Parental permission document, if children younger than 19 years of age are involved
☐ Assent document for children ages 7-11 years
☐ Assent document for children ages 12-18 years
☐ HIPAA Authorization or Request for Waiver if the project involves protected health information (PHI)
☐ Protocol or study design (Please date this document)
☐ Questionnaires/surveys
☐ Interview questions
☐ Diary cards
☐ Other participant handouts: _____
☐ Other (explain): _____

Submit *one copy* of each of the following, as applicable:

☐ If a project is conducted off-campus, include a letter of agreement from the site where the research is being conducted.
☐ Advertising materials, if any
☐ If the research project being submitted has been previously reviewed by a local IRB other than the Creighton IRB, a copy of the approval or disapproval letter from that IRB

13. Principal Investigator's Assurance

The following signature certifies that the principal investigator (PI) understands and accepts the following obligations to protect the rights of research participants. It is the PI's responsibility to:

a. Ensure that the submitted protocol provides a complete description of the proposed research (contains adequate information regarding participants' rights and welfare and ensures that all applicable laws and regulations will be followed).
b. Ensure that risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.
c. Ensure that the consent/permission/assent documents meet all requirements set forth by applicable federal regulations (DHHS, FDA) and Creighton University IRB policies.
d. Educate all involved project personnel as to the research responsibilities associated with the project and the process of informed consent/assent in accordance with all applicable federal and Creighton University guidelines.
e. Ensure that all study personnel who have delegated responsibilities are qualified and have received proper training to fulfill their roles in the study.
f. Ensure that, throughout the course of the study, all research personnel involved in the project conform to the applicable federal regulations and Creighton University IRB policies when conducting the research.
g. Ensure that all valid informed consent/permission/assent documents are obtained from the participants prior to the participants' involvement in the study.
h. Ensure that only personnel identified as investigators in the IRB-approved protocol obtain informed consent from the potential participants.

i. **Secure all research-related records on file and acknowledge that the IRB may review these records at any time.**
j. **Promptly inform the IRB (and any other applicable agency) of any unanticipated problems involving risks to participant or others (including adverse events) associated with the research project as soon as the unanticipated problem is made known.**
k. **Promptly report any proposed modifications to the research project (e.g., amendments, addenda, updates) to the IRB. Modifications will not be initiated until such modifications have been reviewed and approved by the IRB, except to eliminate immediate hazards to participants.**
l. **Inform the IRB immediately of any information that may negatively influence the risk/benefit ratio of participants enrolled in the study.**

I understand that failure to comply with applicable federal regulations and Creighton University IRB policies and procedures could result in suspension or termination of the research project.

_____ _____

Signature of Principal Investigator Date

(Signature must be from the Principal Investigator; the PI may not delegate to other investigators. Signature must be original [not a stamped signature]; a faxed or scanned original is acceptable.)

Creighton
UNIVERSITY

CERTIFICATE OF COMPLETION

PRESENTED TO

Ruomei Wu

RESPONSIBLE AND ETHICAL CONDUCT OF RESEARCH CITI COURSE

This certifies the successful completion of the requirement for Creighton University Responsible and Ethical Conduct of Research Training through the Collaborative Institutional Training Initiative (CITI).

The CITI "Social Behavioral Responsible Conduct of Research" course includes the following elements:

- Research Misconduct
- Data Acquisition, Management, Sharing and Ownership
- Mentor/Trainee Responsibilities
- Responsible Authorship and Publication Practices
- Peer Review
- Collaborative Relationships
- Conflict of Interest and Commitments

Creighton University, in its effort to provide a research environment with the highest standards of professionalism and ethical responsibilities, promotes responsible and ethical conduct of research.

Certified by: Kathleen Diaz Taggart

Kathleen Diaz Taggart
Associate Vice President for Research and Compliance

05-09-2012
Date of Completion

05-09-2016
Date of Expiration