TRIDENT UNIVERSITY INTERNATIONAL

Office of Institutional Research
Institutional Review Board
5757 Plaza Drive, Suite 100, Cypress, CA 90630
Office: (714) 816-0366 ext. 2518 | Fax: (714) 226-9844

Application to Involve Human Subjects in Student Dissertation Research

Part 1: Administrative Information (pre-populated)

1. Title of Protocol:
2. Principal Investigator Information
   - Name:
   - Student ID:
   - Email Address:
   - Phone:
3. College:
4. Dissertation Chair:
5. Submit Date:

Part 2: Study Protocol and Methodology

1. Objective of the Study / Research Questions :_____
2. Does the research involve human subjects? [ ] Yes [ ] No
3. Has any data been collected/obtained for this study to date? [ ] Yes [ ] No

Data Sources/Type

4. Select all categories that apply to this proposed study:
   [ ] Existing data that is publicly available. Specify URL: _____
   [ ] Existing data that is not publicly available. Specify: _____
   [ ] Use of human biological materials
   [ ] Proposal to collect data from participants:
      [ ] In person interview
      [ ] Paper survey
      [ ] Telephone survey
      [ ] Internet survey
      [ ] Use of social networking sites
      [ ] Email/texting survey
      [ ] Observation
      [ ] Focus groups
      [ ] Anthropometric measurements (e.g. height, weight, etc.)
      [ ] Self-health monitoring
      [ ] Other: _____
   [ ] Other
5. Provide details of all procedures selected above: _____

Study Sites:

6. Select all study site locations that apply to this proposed study:
   [ ] Participants' homes
   [ ] Elementary, secondary, or high school. Specify name and location: _____
   [ ] Post-secondary educational institution. Specify name and location: _____
   [ ] Hospitals/Clinics. Specify name and location: _____

[ ] Prisons/halfway houses. Specify name and location: _____
[ ] Nursing homes. Specify name and location: _____
[ ] Online website. Specify URL: _____
[ ] Other locations. Specify name and location: _____

Part 3: Participants, Recruitment, and Compensation (Part 3 is required if collecting data on participants)

1. How many participants do you plan to recruit? _____
2. Age range: From ___ to _____

3. Select all categories of participants included in your study:
   [ ] Languages other than English spoken
   [ ] Healthy adult volunteers
   [ ] Children under 18
   [ ] Employees
   [ ] University Students
   [ ] Prisoners
   [ ] Pregnant women
   [ ] Disabled
   [ ] Other: _____

4. Describe additional inclusion or exclusion criteria for participants in this study: _____

5. Please identify all recruitment methods:
   [ ] Flyers
   [ ] Notices
   [ ] Mailers
   [ ] Online advertisements
   [ ] Email
   [ ] Use of internet social media or online networking sites
   [ ] TV, radio, print advertisements
   [ ] Face-to-face
   [ ] Presentations at meeting
   [ ] Other: _____

6. Please describe each recruitment method used:_____

Part 4: Risks and Benefits (Part 4 must be completed for non-exempt studies)

1. From the list below, please select all of the potential risks that are involved in your study.
   [ ] Use of deceptive techniques
   [ ] Use of private records (such as educational or medical records)
   [ ] Probing for personal or sensitive information in surveys or interviews (e.g. private behaviors, employer assessments)
   [ ] Presentation of materials which some participants may consider sensitive, offensive, or threatening
   [ ] Social or economic risk (reputational, cultural, employability, etc.)
   [ ] Identification of child, spousal, or elder abuse
   [ ] Identification of illegal activity

[ ] Risk of injury or bodily harm
[ ] Other risks: _____
[ ] There are no risks of any kind to any participants enrolled in this study.

2. Describe the nature and degree of the risks or harms selected above. All of the risks/harms must be disclosed in the consent form. _____

3. Describe the steps that will be taken to minimize risks or harms and to protect welfare of participants. Include discussion on how you will handle an adverse or unexpected outcome that could be potentially harmful.
_____

4. Describe any benefits that individuals may reasonably expect from participation. If there are not, state "none."
_____

5. Describe the anticipated benefits of this study to society and/or academic knowledge.
_____

Part 5: Privacy and Confidentiality

1. Will the information for your study involve the collection or access to any of the personal identifiers below? Select all that apply.
[ ] Name
[ ] Student ID
[ ] Date of birth
[ ] Mailing or email address
[ ] Phone or fax numbers
[ ] Social Security number
[ ] Medical records
[ ] License, certificate, or vehicle ID
[ ] IP address
[ ] Biometric identifiers
[ ] Demographic data with fewer than 10 participants
[ ] Photos/images/audio recording
[ ] Any unique identifier not mentioned above: _____
[ ] There will be no access to personal identifiers

Part 6: Informed Consent

1. Please indicate the informed consent document(s) to be used in this study. Provide copies of documents, as applicable
[ ] Not applicable (e.g. existing data)
[ ] Informed consent
[ ] Assent (for children under 18)
[ ] Parental Permission
[ ] Translated Consent/Assent

2. Describe when and where the consent will be obtained: _____

Part 7: Permission from Administrator/Authority at Study Site

1. Was written permission obtained from appropriate administrators at your study site(s)? [ ] Yes [ ] No
2. Did you participate in a service agreement to gain data access? [ ] Yes [ ] No
3. Does your study site(s) have a written policy regarding the accessing data? [ ] Yes [ ] No

4. If yes to #2 or #3, provide applicable website link: _____

Part 8: Financial Conflict of Interest Disclosure

1. Do you have any financial interest related to this research? (e.g. ownership interest, stock, options, compensation related to the research) [ ] Yes [ ] No
2. If yes, please specify: _____

Part 9: Attachments

The following should be uploaded with your application:

-Research Protocol/Methodology Section (from Proposal)
-All surveys, questionnaires, and data collection forms
-List of all data fields accessed from existing data sources
-Written permission from appropriate administrators at the study site (on their department letterhead)
-Other IRB approvals (if applicable)
-Informed Consent/Assent
-All recruitment documents (e.g. flyers, contact letters, advertisements, etc.)

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

I agree to comply with all TUI 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 according to the approved protocol,
- Implementing no changes in 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 the legally effective informed consent from human subjects or their legally responsible representative, and using only the currently approved, stamped consent form with human subjects,
- **Promptly reporting significant or untoward adverse effects to the IRB in writing within 5 working days of occurrence.**

Please enter your full name to agree with the above terms and conditions:

Signed On: *02/04/2014*

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