



## APPENDIX 2 HUMAN SUBJECT RESEARCH REVIEW APPLICATION FORM

### RESPONSIBLE PROJECT INVESTIGATOR (RPI)

The RPI shall serve as the project supervisor and be held accountable for all aspects of the project. TFC students cannot be listed as RPIs. Students conducting research must have member of TFC faculty or staff serve as the RPI.

FIRST NAME:	MIDDLE INITIAL:	LAST NAME:
TELEPHONE:	FAX NUMBER:	E-MAIL:
OFFICE ADDRESS:		
CITY:	STATE:	ZIP:
DEPARTMENT:		
COMPLETE TITLE OF RESEARCH PROJECT:		CODE NAME (ONE WORD):

### INVESTIGATORS

Individuals who are directly responsible for any of the following: the project's design, implementation, consent process, data collection, and data analysis. If more investigators exist than lines provided, please attach a separate list.

FIRST NAME:	MIDDLE INITIAL:	LAST NAME:
TELEPHONE:	FAX NUMBER:	EMAIL:
OFFICE ADDRESS:		
CITY:	STATE:	ZIP:
AFFILIATION: <input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Other: _____		
FIRST NAME:	MIDDLE INITIAL:	LAST NAME:
TELEPHONE:	FAX NUMBER:	EMAIL:
OFFICE ADDRESS:		
CITY:	STATE:	ZIP:
AFFILIATION: <input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Other: _____		

LIST ADDITIONAL INVESTIGATORS ON ATTACHMENT AND CHECK HERE:

### TYPE OF RESEARCH

1. This study is being conducted as part of (check all that apply):

- Faculty Research
- Non-Thesis Student Research
- Doctoral Dissertation
- Honors or Individual Problems Project
- Master's Thesis
- Other: \_\_\_\_\_

### FUNDING

2. How is the research project funded?

- Research is not funded (go to 3)
- Research is funded (go to 2a)
- Funding decision is pending (funding decision has not been made) (go to 2a)

2a. What is the type of funding source? (Check all that apply)

- Federal Grant or Contract
  - Agency Proposal Number \_\_\_\_\_
  - Grant Start Date (MM/DD/YY) \_\_\_\_\_
  - Grant End Date (MM/DD/YY) \_\_\_\_\_
- State or Municipal Grant or Contract
- Private Foundation
- Corporate contract
- Other (specify): \_\_\_\_\_

2b. Who is the point of contact at the funding source?

Name:

Mailing Address:

Telephone:

Email:

### RESEARCH DATES

3a. Date you wish to start research (MM/DD/YY) \_\_\_\_/\_\_\_\_/\_\_\_\_

3b. Date you wish to end research (MM/DD/YY) \_\_\_\_/\_\_\_\_/\_\_\_\_ (End date for data collection and analysis)

Note: Protocols are approved for a maximum of one year. If a proposed project is intended to last beyond the approval period, continuing review and re-approval are necessary.

### RESEARCH LOCATION

4. Where will the experiment or study be conducted? (Check all that apply)

- On Campus (Building and Room Number)
- Off-Campus (Street Address)

### HUMAN SUBJECTS REVIEW

5. Has this project been reviewed by any other committee (college, university, governmental, private sector) for the protection of human research participants?

- Yes
- No

5a. If yes, is TFC conducting the primary review?

- Yes  
 No (If no, go to 5b)

5b. Who is conducting the primary review?

#### STUDY PURPOSE

6. Describe the rationale for the research project.

#### SUBJECTS

7. What will be the maximum number of subjects in the study?

7a. Indicate the approximate number of:

Males      Females

7b. What is the age of subjects? (Check all that apply)

- Children (1-17 years old)  
 Adults (18-65 years old)  
 Elderly (66-years and older)

7c. Will students be enrolled in the study? (Check all that apply)

- Undergraduate students\* – Department:  
 Advanced students – Department:

\*If students are under 18 years old, parental consent must be obtained.

7d. Provide rationale for the choice of subjects. Enumerate any additional defining characteristics, including age, of the subject population. (e.g., symptomatology, history, socio-economic status).

#### VULNERABLE SUBJECTS

8a. Are research subjects being used whose ability to give informed voluntary consent may be in question? (e.g., children, persons with AIDS, mentally disabled, psychiatric patients, prisoners.)

- Yes (If yes, explain the procedures to be employed to enroll them and to ensure their protection).  
 No

8b. What type of vulnerable subjects are being enrolled? (check all that apply)

- Critically Ill Patients  
 Mentally Disabled or Cognitively Impaired Individuals  
 Prisoners  
 Physically Handicapped  
 Pregnant Women

- Children
- Other:

### RECRUITMENT

9. How will participants be recruited? (Please submit a copy of the sign-up sheet, newspaper advertisement, or any other protocol or procedure which will be used to recruit subjects.)

- Internet
- Newspaper/radio/television advertising
- Posters/brochures/letters
- Other:

Comments:

### INCLUSION AND EXCLUSION CRITERIA

10. Are subjects equitably chosen for participation in the study? (no one group is excluded without justification)

- Yes
- No (If no, specify criteria and justify in detail below.)

10a. Does the study require special evaluation and screening of potential subjects to determine their appropriateness for inclusion in the study?

- Yes (If yes, briefly elaborate on the screening process and attach the screening questionnaire.)
- No

### EXPERIMENTAL OR STUDY PROCEDURES

11. Describe the experimental or study procedures that will be followed. (Include a succinct, but comprehensive statement of the methodology relating to the human subjects. You are encouraged to include a discussion of statistical procedures used to determine the sample size.)

11a. Will any aversive or painful procedures be employed (e.g., shock, the threat of shock or punishment, experimentally or study induced stress?)

Yes (If yes, specify and justify in detail below.)

No

11b. Will the deliberate deception of research participants be involved as part of the experimental or study procedure?

Yes (If yes, explain the nature of the deception, why it is necessary, any possible risks that may result from the deception, and the nature of the debriefing with specific reference to the deception.)

No

Attach copies of the following items:

Research Protocol(s)

Questionnaire

Copies of any instructions or debriefings given

If the research is part of a research proposal submitted for federal, state or external funding, submit a copy of the FULL proposal.

## COMPENSATION

12. How much time will be required of each subject?

12a. Will research subjects receive course credit for participating in the study?

Yes (If yes, please explain in comments section.)

No

Comments:

12b. Are there any other forms of compensation that may be used? (e.g. Money)

Yes (If yes, please explain in comments section.)

No

Comments:

12c. Are there any penalties for subjects who do not show up for a research session?

Yes (If yes, please explain in comments section.)

No

Comments:

## INFORMED CONSENT

13. Do you intend to obtain informed consent from subjects?

- Yes (please answer question 13a)  
 No (please complete: Request for Waiver of Consent Form)

13a. Describe the procedures that will be used to obtain Informed Consent and attach the Informed Consent Document (follow the guidelines for preparation of the University Informed Consent Form).

Note: Subjects MUST be given a description of the procedures and rationale for the study to the best extent possible. The benefits and ANY risks associated with participating in the study MUST be enumerated. The subjects MUST be informed of their right to terminate the experiment at any time. If there is no risk associated with the study and participants' signature on the informed consent sheet is the only identifying information about the name of the subject, then the subjects' signature may not be necessary.

## RISKS

14. What are potential risks of the research? (Check all that apply)

- Physical harm  
 Psychological harm  
 Release of confidential information  
 Other:

14a. Describe any potential risks to subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject's physical well-being, privacy, dignity, emotions, employability, and criminal and legal status. A detailed, comparative statement of the risk (harm or likelihood) must also be described in the consent form.

Please attach the following (if you have developed them)

- The script by the researcher to disclose potential harm and likelihood (risk) prior to the subject's choice to participate.

## BENEFITS

15. Assess the potential benefits that may accrue to the individual subject as well as to others as a result of the proposed study. Do the potential benefits justify the possible risks involved? Although you may mention general benefits to society, such speculative benefits should not be presented to a subject as a direct benefit for informed consent.

### PROTECTION OF ANONYMITY

16. Describe in detail the procedures for protecting the anonymity (meaning that no one will ever be able to know the names) of the research subjects. If anonymity is impossible, then describe in detail the procedures for safeguarding data and confidential records. These procedures relate to how well you reduce the risk that a subject may be exposed or associated with the data.

### DRUGS OR DEVICES

17. Will any drugs, devices, chemical or biological agents be used with the subjects?

- Yes (If yes, please attach Drugs, Agents, and Devices Form)  
 No

### BIOLOGICAL MATERIALS

18. Will this research involve the collection, analysis, or banking of human biological materials (cells, tissues, fluids, DNA?)

- Yes (If yes, please attach Biological Materials Form)  
 No

### TRAINING

19. Briefly explain the nature of the training and supervision of anyone who is involved in the actual data collection, research design, or in conducting the research. This information should be sufficient for the IRB to determine that the RPI and investigators possess the necessary skills or qualifications to conduct the study.

### Human Subjects and HIPPA Training

20.a. The RPI must document completion of Human Subjects Training. (Attach a copy of the RPI's NIH Certificate for "Protecting Human Research Participants" or the CITI Program Certificate of completion.)

Date RPI completed Training:

20.b. RPI's who propose studies with patient populations must document HIPPA training by accessing the NIH booklet entitled "Protecting Personal Health Information in Research: Understanding the HIPPA Privacy Rule" at: [http://privacyruleandresearch.nih.gov/pr\\_02.asp](http://privacyruleandresearch.nih.gov/pr_02.asp). and must submit an attachment to the review application stating that the material has been read and will be adhered to in the proposed research. The attachment must include the date the material was read, which must be within the 12 months prior to the application. (If you are submitting this attachment with your application the RPI must initial here: \_\_\_\_\_)

### PLEASE NOTE:

- You may begin research when the TFC Institutional Review Board gives you final WRITTEN notice of its approval.
- You MUST inform the committee of ANY adverse event, changes in the method, personnel, funding, or procedure.
- At any time, the committee reserves the right to re-review a research project, to request additional information, to monitor the research for compliance, to inspect the data and consent forms, to interview subjects that have participated in the research, and if necessary to terminate a research investigation.

**SIGNATURE & DATE**

Responsible Project Investigator (Must be original signature):

Date: