**The University of Tulsa Institutional Review Board**

**Exempt Protocol Application Instructions**

Your TU IRB Exempt application should consist of the following:

1. A completed and signed TU IRB Exempt Checklist for PIs with an Exempt determination.
2. A completed TU IRB application form, including a fully signed and dated signature page.
3. Copies of IRB training completion certificates for all personnel listed on this IRB application form. …**\* include as separate documents**
4. Copies of any instruments: questionnaires, test instruments, interview questions, etc…**\* include as separate documents**
5. Any letters/emails of approval from cooperating institutions and/or internal/external organizations (additional external approvals may be submitted at a later time as long as the IRB is aware of these additional approvals and that you are aware that your study cannot commence until the TU IRB is in receipt of all your necessary approvals)

**Your TU IRB Exempt Application is not considered complete unless the IRB Application has been reviewed, approved and signed by the PI (principal investigator) and Faculty Mentor (if the PI is a student).**

 **\*Faculty Mentor** – Any undergraduate or graduate student PI submitting a human subject research protocol must be under the direction of a Faculty Mentor throughout the life of the research study *and* the Faculty Mentor must be current with their IRB training at the time of the protocol submission.

**\*Research Personnel “engaged” in human subjects research –** Those working on a protocol where they will be doing any of the following: intervening or interacting with subjects; collecting consent or data; working on or having access to identifiable data.

**Complete protocol applications should be submitted to**:

researchcompliance@utulsa.edu, 918-631-3310

**~ GENERAL INSTRUCTIONS AND SUBMISSION / REVIEW TIMELINES ~**

* Please follow the *italicized* and/or bracketed [ ] instructions on all the IRB Application forms **AND DO NOT DELETE any instructions or questions.**
* **DO NOT** **DELETE** **any sections** of this application form and **DO NOT DELETE** any instructions after each section heading/sub-heading. All sections should either be addressed or stated as “non-applicable” (N/A).
* For ***all*** protocols, please allow up to ten working days for the initial review. During winter and spring breaks, holidays and in the summer, the review process may take longer.

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* **Consent for Exempt Protocols**:
* Oral or written consent can be used;
* TU Informed Consent Form (ICF) templates are available but not required to use or submit;
* If used, TU ICF template language can we altered and whole sections deleted;
* Required Minimal Informed Consent Information:
	1. That the activity is research;
	2. That participation is voluntary; and
	3. A description of the participation activities and approximate participation time.

**The University of Tulsa Institutional Review Board**

**Exempt Application for Use of Human Subjects in Research**

**Principal Investigator (PI):**

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Campus (not lab) or Cell Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-Mail address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Graduate Student? Yes [ ]  No[ ]  Undergraduate Student? Yes[ ]  No[ ]

***\*\*All Principal Investigators (PIs), Co-Investigators (Co-PIs) and ALL other research personnel ‘ENGAGED’ in human subjects research MUST be listed on this IRB application and MUST have a current IRB training certificate at the time of submission. In addition, any researchers added to this protocol after approval must make this request to the ORSP and hold a current IRB training certificate before they can be added to this protocol.***

**Co-Investigator(s)**

Include name and department. If student(s), please indicate if graduate or undergraduate student and department(s):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ALL other research personnel “ENGAGED**” in human subjects research. If student(s), please indicate if graduate or undergraduate student and department(s):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Have all research staff listed for this study, completed the required IRB CITI training course? Yes[ ]  No[ ]

***\*Please attach completion certificates with IRB application paperwork***

If you are a student PI, please provide the following:

Faculty Mentor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project Information:**

Project title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Project time period: Proposed Start: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to Estimated End Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\*Estimated End Date: *When all participant research activities are complete, all identifying data or links to identifiers have been destroyed, leaving only de-identified data***

Are you requesting internal or external funding support for this project? Yes \_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_

[ ]  internal funding (university/college/dept./start-up funds) [ ]  external funding (federal/state/private) [ ]  n/a

***\*If yes, sponsor’s name and award number or source of funding***:

**Source of subjects:**

*[Include all research sites, selection and/or exclusion criteria, and if more than one kind of participant pool with different circumstances, list each participant pool separately]*

**Critical Questions:**

**Does the proposed project:** **Yes No**

1. Expose participants to the possibility of injury (physical, psychological, or social)

or any stress or discomfort, exposure to harmful stimuli? [ ]  [ ]

1. Besides the research personnel listed on this application, does this research

involve participants interacting with any other individuals? [ ]  [ ]

1. Involve the attachment of any apparatus to participants? [ ]  [ ]
2. Involve the administration of drugs to participants? [ ]  [ ]
3. Involve the recruitment of student-athletes or university faculty/staff? [ ]  [ ]
4. Involve the request of private health information (PHI) from a HIPAA

covered entity? [ ]  [ ]

1. Involve conducting research or recruiting subjects outside of the United States,

on tribal lands or specifically targeting Native Americans? [ ]  [ ]

1. Involve protected groups such as: children, pregnant women, fetuses, neonates,

prisoners, or others that may be vulnerable to coercion or undue influence? [ ]  [ ]

1. Involve paid compensation or incentives to participants? [ ]  [ ]
2. Involve any form of deception? [ ]  [ ]
3. Involve asking participants to reveal any embarrassing, sensitive or

confidential information about themselves/others or use of audio/visual recordings? [ ]  [ ]

1. Involve the request of individual student academic records (FERPA)? [ ]  [ ]
2. Involve a clinical trial and registering the study on ClinicalTrials.gov? [ ]  [ ]

***If you answered “No” to all of the above questions, mark here:*** [ ]

***If you answered “Yes” to any of the Critical Questions, provide additional information/explanations on each topic and how you plan to minimize any risks/ provide additional protections.***

 Question #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Question #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Detailed Description of the Study:** *[Insert your protocol information under each heading and/or sub-heading and below the instructions* ***(DO NOT DELETE the instructions/questions under each heading/sub-heading)]***

***[Sections A-H are mandatory sections. Complete sections I – K if applicable*** *to your research study****]***

**A. Purpose/Objectives**

*Explain the overall purpose of your study and its primary objectives, including the importance of the knowledge expected to result.*

**B. Recruitment Methods**

**1*. Describe the participant pool(s) you will be recruiting****.* ***Answer each question below:***

1. *What is the estimated number of participants?*
2. *List all sites where research will be conducted:*
3. *In person, privately scheduled appointments with a researcher or in groups or virtual (via internet)?*
4. *Describe the selection/exclusion criteria such as age, gender, health conditions, etc…*

**2.** ***Explain your recruitment methods:*** *SEE “Research Ads –Guideline”* ***Answer each question below:***

1. *What is the estimated recruitment period?*
2. *Explain recruitment procedure(s) (ex. email invite, classroom visit by PI, etc.)*
3. *List all types of recruitment materials you might use, such as: SONA postings, flyers, scripts, social media page, etc.[send a draft of each with this application - \*SEE “Research Ads –Guideline”]*

**C. Research Protocol**

***Describe the study and procedures you will use, including a detailed, chronological description of the procedures****.* ***Answer each question below:***

1. *How will the researcher(s) meet/interact with the participants?*
2. *What are ALL of the activities that subjects will be asked to do, to participate in this study? List all that you are asking of participants if they consent to participate:*
3. *Will participants need access to a device (smart phone, cell phone, tablet, etc.)? Use wearable technology (ex. Fitbit)? Or report data from wearable technology (enter or screen shot of app/dashboard)?*
4. *Where will the research be conducted? Privately scheduled appts./session or in groups? How many appts./sessions? How long will each appointment/session take? Total participation time?*

**D. Confidentiality**

***Clearly and concisely describe the procedures you will use to ensure confidentiality of the data and protecting the identity of study participants. Answer each question below:***

1. *Will subjects will be identifiable to the researcher(s)?*

1. *How will participants’ identities be protected? Specifically address how signed consent forms will be secured.*
2. *Will researcher(s) be able to link responses back to individual participants? Explain why or why not.*
3. *Will researchers need to create a link (a digital or paper document, ‘master list’) between the subjects and their data (even if just for a short period of time)?*

*If so, please explain this link, what info. is included in the document and where this document will be secured; for how long and approximate destroy date, if applicable?*

1. *Explain the procedures in place to protect confidentiality of the data: As it’s being collected? During transport (physical or digitally)? (ex. stored in locked cabinets and give detail on location; who has access to the secure location; for how long).*
2. *If the research is being conducted using digital technologies? (internet, survey servicer, cloud storage, apps, multimedia messaging service-MMS)*
3. *Address how confidentiality or anonymity is achieved/maintained using these technologies.*

***\*\* NOTE: You will need to add a disclaimer statement that the internet website or servicer has specific privacy policies of their own and that if participants have any questions/concerns they should contact them directly AND then include that link. This disclaimer statement & link needs to be included on any consent forms\*\****

1. *Will project publications (theses, papers, videotapes, presentations, etc.) allow identification of individual participants?*

**E. Potential Risks to Participants:**

 ***Explain any reasonable, foreseeable risks or discomforts to participants and how you plan to minimize them. Identify any procedures that are experimental.*** ***Pick 1 of the 2 statements below that apply to your study and delete the other:***

 **(1)** There are no known risks to participants in this study.

 **or**

 **(2)** [*Explain any possible physical or psychological risks.]*

**F. Anticipated Benefits:**

 ***List any direct or indirect benefits to the participants and/or society associated with this study.***

***[Pick 1 of the 2 statements below that apply to your study and delete the other.*** *NEVER include any compensation or extra credit in this section. (Payment is NOT a benefit. USE the payment/compensation section)*

* ***Any direct benefits for participants?*** **(1)**There are no direct benefits to participants in this study.**or (2)** [*Explain their direct benefit(s)]*
* ***Any indirect benefits to participants or others?*** *Explain any indirect benefits to participants or others (society, etc.).*

**G. Measures:**

 *Use this section to list and briefly explain all instruments used in this research study to include: questionnaires,*

##  *tasks, test instruments, interview questions, etc… If no measures are being used, please explain.*

 ***\*submit a draft of all instruments separately, with this application paperwork.***

**H. Compensation/Incentives:**

 ***\*If this section is not applicable to your study mark here:*** [ ]  ***If applicable, answer all items below:***

1. *List any compensation/incentives such as payments, gifts or extra credit offered for participating in this study:*
2. *If course extra credit is being offered, it is required that you include a non-research extra credit option(s)? (This extra credit option has to be comparable in terms of time and effort as the research participation.)*
3. *Explain if participants still receive the entire compensation/incentive if they withdraw early or if they will receive a portion of the compensation/incentive for what they’ve completed before they withdrew. Explain any criteria to receive the full compensation amount and explain any breakdown of incremental compensation and the criteria that the increments are based on.*
4. *If there is raffle/lottery incentive, please include your justification why a raffle/lottery is being requested instead of a universal incentive and you must state the estimated odds of winning on this application in simple terms (ex. 1 in 10 chance to win) and in the Informed Consent Form.*

\***ALL CHECK AMOUNTS AND CASH OR GIFT CARDS OVER $25** **PLEASE NOTE:** The TU Controller’s Office requires identifying information to issue checks of any dollar amount or to track cash payments or gift certificates over $25 to payees. In those cases, the Confidentiality section of the Informed Consent Form must inform participants that they will be asked to provide their Name, Address and Social Security Number to receive compensation. This information will be provided to the Controller’s Office at the time of payment (payment/compensation is made via a check) or at the end of the year with the link between the particular project and the participant removed. Please check with the Coordinator of Research Compliance for applicable forms to use.

**I. Compensation for Injury:**

 ***\*If this section is not applicable to your study mark here:*** [ ]  ***If applicable, answer all items below:***

*(For research involving more than minimal risk (Full Board studies) explain whether or not any compensation or medical treatment is available if injury occurs. If compensation or treatment will be provided, describe the nature of the compensation and/or treatment. If no compensation will be available, make that clear in the consent form. Explain how the subject can obtain additional information if necessary.)*

**J. Additional Approvals you will be seeking:**

 ***\*If this section is not applicable to your study mark here:*** [ ]  ***If applicable, answer all items below:***

 *(Use this section to briefly list any and all other approvals (external) that you will be seeking in*

##  *order to execute your protocol.*

 *Will you need additional external approvals if you will be recruiting subjects or working on this research at a different location(s) other than The University of Tulsa? Will you have a Co-PI on this study from another institution? Who may be “engaged” in the research: recruiting, interacting with subjects, obtaining consent or recruiting subjects?*

 *\*****Please see the Coordinator of Research Compliance for more information on university policies and procedures***

 ***regarding other additional internal or external approvals needed.***