

**I**nstitutional **R**eview **B**oard Office

The University of Texas at El Paso

 Office of Research and Sponsored Projects

**Exemption Request Application**

***Instructions:***This form must be reviewed and completed in its entirety. This form is to be submitted to the IRB only when an investigator is contemplating the initiation of a research or capstone project, which, in the investigator’s judgment, may be exempt from full IRB review. Please type and submit this form along with finalized copies of all project related materials via [IRBNet](http://www.irbnet.org/). Study information sheets can be used in lieu of consent forms for exempt research projects. See forms section for more information.

Attention to these elements will facilitate the IRB’s review of your project. The IRB will then determine whether the activity is covered by the allowable Exempt regulations. Research activities are exempt from regulations for the protection of human research subjects when they are considered minimal risk ( the probability or 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 (as defined by 45 CFR 46.101), and the ONLY involvement of human subjects falls within one or more of the exempt categories.

The Federal Office for Human Research Protections (OHRP) has allowed for **six exempt categories**.

The **exempt categories** outlined below are based solely on methods of research, and do not take the level of risk into consideration. Although most exempt research requires no further oversight to be conducted ethically, some exempt research raises ethical concerns or requires measure to protect participants. As such, the IRB will not consider any research exempt that does not fulfill ethical principles reflected in the Belmont Report. These three basic ethical principles are:

**Respect for Persons (autonomy**)- individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection.

**Beneficence-** human participants should not be harmed and the research should maximize possible benefits and minimize possible harms.

**Justice**- the benefits and risks of research must be fairly distributed.

Research that otherwise would be exempt by federal regulations that raises ethical concerns or requires measures to protect participants may be denied and/or moved to a higher level of review.

For further guidance or assistance, please contact the IRB office at (915) 747-7693 or by email at irb.orsp@utep.edu.

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| 1. **Project Information**
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| **Project Title** |       |
| **Principal Investigator****(Last Name, First Name)** |       |
| **University Title** | [ ]  Faculty/Staff [ ]  Student |
| **Department** |       |
| **Co-Investigator****(Last Name, First Name)** |       |
| **University Title** | [ ]  Faculty/Staff [ ]  Student |
| **Protocol Title:** |       |
| E-mail Address |       | Phone Number |       |
| **Human Subjects Research Training Completed:** | [ ]  Yes [ ]  No | Anticipated Start DateAnticipated End Date: |       |

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| If the **Principal Investigator is a student,** the faculty advisor must indicate knowledge and approval of this submission. By electronically signing the package in IRBNet, the faculty advisor certifies that the study is under their direct supervision and that the faculty advisor is responsible for ensuring that all provisions of the IRB approval are complied with by the investigator. |

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| 1. **Type of Project**

*Check all that apply*  |

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| [ ]  | Faculty Research | [ ]  | Thesis | [ ]  | Dissertation |
| [ ]  | Presentation/Conference | [ ]  | Capstone | [ ]  | Internal Evaluation/Non-Publishing |
| [ ]  | Funded-Source:       | [ ]  | Publication:       | [ ]  | Other:       |

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| 1. **Applicability**
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| **C1. Does the study protocol include children as research subjects?**  (see 45 CFR 46.101(b)(2))  | YES [ ]  NO [ ]  N/A [ ]  |
| **C2. Does the study protocol include prisoners, fetuses, pregnant women, or human in vitro fertilization?** | YES [ ]  NO [ ]  N/A [ ]  |
| **C3. Does the protocol involve more than minimal risk?** | YES [ ]  NO [ ]  |
| **C4. Does the protocol involve deception?** | YES [ ]  NO [ ]  |
| **C5. Does the protocol include cognitively impaired participants as research subjects?** | YES [ ]  NO [ ]  |

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| **If you answered yes to any of the above, the submission does not qualify for exemption. Please fill out a full study protocol.**  |

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| 1. **Exempt Research Categories**

*Check the applicable category below. Only answer questions related to the applicable category.* |

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| [ ]  **Category 1 EDUCATIONAL**1. Will the researchers use their current students or trainees as participants?

YES [ ]  NO [ ] Please explain what additional measures will be taken to ensure participants do not feel pressured or coerced during recruitment for or participation in the research:       |
| [ ]  **Category 2 SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR**1. Will the researchers use their current students or trainees as participants?

YES [ ]  NO [ ] 1. Will the research involve children in survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed?

 YES [ ]  NO [ ]  **If yes, this study does not meet the criteria for exemption.** 1. Will you record information in a way that human subjects can be identified, directly or through identifiers (coded) linked to the subjects?

 YES [ ]  NO [ ] 1. Could any disclosure of the subjects’ responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, or reputation?

YES [ ]  NO [ ]  |
| [ ]  **Category 3** **ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE** |
| [ ]  **Category 4 EXISTING DATA**1. What is the source of the data?

 [ ]  Publicly available database [ ]  Student Records Include Link:       CIERP will be providing dataset: YES [ ]  NO [ ]  [ ]  Medical or Private Records [ ]  Another PI/Researcher collected it in the past Do you have permission to use this data? NO [ ]  YES [ ]  If yes, describe how and attach documentation indicating permission. 1. Will this data be stripped of any identifiers?

 YES [ ]  NO [ ] 1. Will you be using a data collection form? Attach documentation and/or list data points.

 YES [ ]  NO [ ]  Please note that HIPAA prohibits the collection of specified identifiers such as name, street address, telephone/fax numbers, e-mail address, URLs & IP addresses, social security numbers, certificate/license number, vehicle/serial identifiers and full face photos. |
| [ ]  **Category 5** **ONLY USED BY OR WITH THE APPROVAL OF GOVERNMENT AGENCIES** |
| [ ]  **Category 6 TASTE/FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE** |

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| 1. **Project Site(s):** *Check all that apply This includes subject recruitment, subject enrollment, data collection, and data analysis*
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| [ ]  | Project will be conducted entirely at UTEP.  |
| [ ]  | Research will be conducted at another institution.\*Project will be reviewed by another IRB and/or Ethics CommitteeProvide the institution name and contact person:       |
| [ ]  | Other\*:       |

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| \*Please include applicable Authorization Letter(s) indicating permission to conduct project in the submission package |

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| 1. **Ethical Considerations:**
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| **E1. Does this project include inclusion and exclusion criteria?****IF yes, please describe:**      | YES [ ]  NO [ ]  N/A [ ]  |
| **E2. Will you be audio or video recording during any portion of this project?****IF yes, please describe:**      | YES [ ]  NO [ ]  N/A [ ]  |
| **E3. Does the project pose any risk to the individual(s)?****IF yes, please describe how the risk/benefit ratio has been weighed and explain how you will address this concern:**      | YES [ ]  NO [ ]  |
| **E4. Will subjects benefit from participating in the research? (compensation is not a benefit)****Describe and assess potential benefits to be gained by participants (if any) and the benefits that may accrue to society in general:**       | YES [ ]  NO [ ]  N/A [ ]  |
| **E4. Is there a possibility of coercion or undue influence?****IF yes, please describe how you will address this concern:**      | YES [ ]  NO [ ]  |
| **E5. Will subjects be compensated (payment, incentives, extra credit, etc.)?****IF yes, please describe:**       | YES [ ]  NO [ ]  N/A [ ]  |
| **E6. Will this project use social media, internet websites, or any other web based software?****IF yes, please describe and include link(s):**       | YES [ ]  NO [ ]  |
| **E7. Will identifiable data be made available to anyone other than the Principal Investigator and approved study staff?****IF yes, explain who and why they will have access to the identifiable data:**      | YES [ ]  NO [ ]  N/A [ ]  |
| **E7. Will the results of the project be disseminated? Check all that apply.**[ ]  **Publication** [ ]  **Presentation**  | YES [ ]  NO [ ]  N/A [ ]  |

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| 1. **Literature Review:**

*In this section describe the significance of the proposed project. Provide appropriate references.*  |

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| 1. **Summary of Project Activity:**
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| **Briefly state the purpose of this research project and your research question(s):**      |

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| **What is the project goal(s)? Please include the specific population geared to benefit from this project:**      |

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| **Describe the informed consent process plan. How will participants be fully informed of this research prior to their participation and how will their voluntary consent be documented. \* Note: Please SUBMIT a copy of the form(s).**       |

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| **Describe how the project will be implemented. Describe the task(s) subjects will be asked to perform. List what procedures you will follow and what the study participants will be exposed to. *Please provide details (# of subjects, procedures, duration, etc.).* Alternately, describe the study plan for a project working with existing data (# of files, specimens, time frame, etc.)**      |

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| **Describe how the project team will protect the privacy of study participants:**     **Could the information obtained or recorded about subjects place them at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, insurability, or reputation?** **YES** [ ]  **NO** [ ]  **N/A** [ ] **If yes, please explain:**       |

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| **Describe how the project team will collect, manage, and analyze data.** **Describe provisions that will be taken to maintain confidentiality of the data. Will it contain subject names or images? (e.g surveys, video, audio tapes, database)**      **Describe the security plan for data, including where data will be stored, and for how long, noting that you may not keep identifiable data indefinitely (i.e., password protection, encrypted, locked filing cabinet, etc.):**            |

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| **ASSURANCES – Conflict of Interest and Fiscal Responsibility**All UTEP researchers (faculty, staff, and students) and outside collaborators who will be conducting human subjects’ research (intervention and/or interaction) must complete human subject research ethics training in order to conduct research with human participants. |
| Do you or any person responsible for the design, conduct, or reporting of this project have an economic interest in, or act as an officer or director of any outside entity whose financial interests may reasonably appear to be affected by this project? If yes, please explain any potential conflict of interest       | YES [ ]  NO [ ]   |
| Do you or any person responsible for this project have existing financial holdings or relationships with the sponsor of this study? If yes, please explain any potential conflict of interest       | YES [ ]  NO [ ]  N/A [ ]  |
|  **Principal Investigator Certifications:**  |
| **With this submission I certify that:**[ ]  I agree to fully comply with the ethical principles and regulation regarding the protection of human subjects in research.[ ]  I agree that the information provided in this form and all other supporting documents are accurate and complete.[ ]  I accept responsibility for making sure all study personnel involved in the project have been appropriately trained. PI affirms responsibility for keeping training records on file for all study personnel. [ ]  I understand that any changes in procedure with affect to participants must be submitted to the IRB for written approval prior to their implementation. Furthermore, I understand that any adverse events and significant changes in risk for participants must be immediately reported in writing to the UTEP IRB.Copies of all required documentation of consent (if applicable) and any related to this research are securely stored as outlined above in       (UTEP building and office number).  |