

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

The University of Texas at El Paso

 Office of Research and Sponsored Projects

**Research Protocol Application**

***Instructions:***This form must be reviewed and completed in its entirety. All applications for review should contain the information presented in paragraphs. Indicate N/A when not applicable. A complete description of the planned research needs to be submitted in order to determine if all regulatory policy requirements have been met.

As such, the IRB will not consider any research 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.

Please type and submit this form along with finalized copies of all project related materials via [IRBNet](http://www.irbnet.org/). Attention to these elements will facilitate the IRB’s review of your project.

For further guidance or assistance, please contact the IRB office at (915) 747-6590 or by email at irb.orsp@utep.edu.

For more information, please see the [Investigator Manual for Human Subjects Research.](https://www.utep.edu/orsp/human-subjects-research/_Files/docs/Investigator%20Manual%20for%20Human%20Subjects%20Research_FINAL_Jan%202019.pdf) (Ctrl+click to follow the link)



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|  **Project Information** |
| **Protocol Title:** |       |
| **Principal Investigator****(Last Name, First Name)** |        |
| **University Title** | [ ]  Faculty/Staff [ ]  Student |
| **Department** |       |
| **E-mail Address** |       | **Phone Number** |       |
| **Human Subjects Research Training Completed:** | [ ]  Yes [ ]  No | **Anticipated Start Date****Anticipated 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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| **If PI is a student, list Faculty Advisor/Sponsor** *Remember to electronically share the submission package with this person.*  |
| **Faculty Advisor****(Last Name, First Name)** |       |
| **University Title** |        |
| **Department:** |       |

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| **E-mail Address** |       | **Phone Number** |       |
| **Human Subjects Research Training Completed:** | [ ]  Yes [ ]  No |

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| Additional Study Personnel Project Team Members- UTEP affiliation |
| Name: | **Title:** | **Role****(check all that apply)** |
|        |       |  **1 2 3 4 5** [ ]  [ ]  [ ]  [ ]  [ ]  |
|        |       |  **1 2 3 4 5**[ ]  [ ]  [ ]  [ ]  [ ]   |
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| External Personnel *Please list external study team members who will interact with participants or access identifiable data* |  |  |
|       |       |  **1 2 3 4 5**[ ]  [ ]  [ ]  [ ]  [ ]   |
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| **Project team member’s role on the project (1-5)** |
| 1. **Involved in the recruitment process of participants monitoring**
2. **Involved in the consent process with participants**
3. **Involved in data collection/ entry**
4. **Involved in data analysis**
5. **Involved with the project. No human subject interaction and/or working with identifiable data.**
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| **Type of Project***Check all that apply*  |

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

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|  [ ]  Funded | Federal [ ]  Non-Federal [ ]  Other [ ]   |
| **Source:** |        |

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| All new federally funded human subjects research studies must comply with the revisions to the U.S. Department of Health and Human Services (DHHS) human subjects research regulations.**Principal Investigators (PIs) are responsible for notifying the IRB if there is a change in funding.** |

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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.  |
| [ ]  | 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:       |
| [ ]  | Multi-Site Study\*: Is UTEP the lead institution? YES [ ]  NO [ ]  If NO, list the lead institution:       |
| [ ]  | Other\*:       |
| [ ]  | International –*Please complete section below.* |

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| \*Please include the Site Authorization Letter indicating permission to conduct project in the submission package |

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| **International Research:***Identify where the research will be conducted. Provide information regarding local customs, laws, and regulations of the site(s). Clarify is your research requires local ethics committee review and approval and/or if permission is required from a government entity.*  |

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| 1. **Ethical Considerations:**
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| **B1. Will this project be conducted anonymously? (Note, in person studies and/or collection of IP addresses are not anonymous)****IF yes, please describe how anonymity will be preserved throughout the duration of the study:**      | YES [ ]  NO [ ]  |
| **B2. Does the study protocol include children as research subjects?**  | YES [ ]  NO [ ]   |
| **B3. Does the study protocol include a protected group(s)? ( UTEP employees, UTEP students)** | YES [ ]  NO [ ]  |
| **B4. Does the study protocol include prisoners, fetuses, pregnant women, human in vitro fertilization, or persons with impaired decision making?****Identify:** | YES [ ]  NO [ ]   |
| **B5. Does the study specifically select economically/educationally disadvantaged individuals?** | YES [ ]  NO [ ]  |
| **B6. Does the protocol involve more than minimal risk?** | YES [ ]  NO [ ]  |
| **B7. Does the protocol involve deception?** | YES [ ]  NO [ ]  |
| **B8. Does the protocol involve persons with impaired decision making?** | YES [ ]  NO [ ]  |
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| 1. **Hypothesis, Objectives, or Goals of the Project:**

*Clearly state the purpose of the study (research questions and/or study objectives).*  |

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| 1. **Background and Significance:**

*Describe relevant background literature to support the rationale for doing this study. This rationale should provide sufficient information to justify the study. Describe the potential benefit for individual subjects or society at large. It should be limited to no more than two to three pages.* |

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| 1. **References/Literature Review:**

*List all references cited in the protocol and/or pertinent to the study.* |

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| 1. **Research Method, Design, and Proposed Statistical Analysis:**

*Provide a* ***brief*** *overview of your research methodology (e.g. experimental, correlational, qualitative) and specific study design and your proposed analysis of the research data.* |

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| The following sections outline types of research activities. Please check the box(es) **ONLY** if **all** activities involving human subjects falls into one or more the applicable categories.  |

 **Behavioral Study Activities**

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| [ ]  | Research conducted in established or commonly accepted educational setting, involving normal educational practices. (E1) *This category may include research on effectiveness as well as comparisons about educational strategies, techniques, curricula or classroom management. Educational tests, such as cognitive, diagnostic, aptitude, achievement tests*Notes: * The research must not adversely impact students’ opportunity to learn required educational content.
* The research must not adversely impact the assessment of educators who provide instruction.
* An information sheet or abbreviated consent document should be used
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| [ ]  | Research that ONLY includes surveys, interviews, focus groups, or observation of public behavior with adults who can consent for themselves and covering benign topics. (E2) (I-LR)(FR) Notes: * The term “benign” describes activities that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive.
* Interventions are not allowed.
* An information sheet or abbreviated consent document should be used.
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| [ ]  | Benign research on perception, cognition, motivation, communication, social behavior, behavioral games or minimal risk performance tasks. (E3)(LR)(FR) Notes: * The term “benign” describes activities that are brief in duration, not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive, and not likely to have a lasting adverse impact.
* An information sheet or abbreviated consent document may be used.
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| [ ]  | Secondary research use of identifiable private information or identifiable biospecimens originally collected for other purposes. (E4) Notes:* When the identifiable private information or biospecimens are publicly available;
* The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact the subjects or try to re-identify subjects.
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| [ ]  | Taste/Food quality evaluation and consumer acceptance. (E6)  |

*General Notes:*

The above research may involve randomization between groups if disclosed to participants.

The above research may be audiotaped, if the subject agrees, if identities are not shared, and the confidentiality of the information is properly protected.

Exempt category 5 is not listed as it applies to projects conducted or supported by or subject to the approval of Federal department and agency heads. Please contact the IRB office if you feel your project meets this criteria.

UTEP will not implement exemption categories 7 & 8 at this time.

 **Biomedical Study Activities**

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| [ ]  | Prospective collection by non-invasive procedures such as ultrasound, MRI without contrast, Doppler, MEG, EEGs, ECGs, eye tracking |
| [ ]  | Moderate exercise, muscular strength testing, body composition assessment in healthy adults (Ex4) |
| [ ]  | Non-invasive collection of biospecimens (Ex3)  |
| [ ]  | Non-invasive tests (body composition, BP, pulse)(Ex4)  |
| [ ]  | Collection of blood for research purposes only from heel stick, ear stick, finger stick or venipuncture, provided (Ex2): * Total amounts in healthy adults do not exceed 550 ml in an 8 week period or collection may not occur more frequently than 2 times per week; or
* For other adults, considering the age, weight and health of participants and collection procedure, the total amount drawn does not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and does not occur more frequently than two times per week.
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| **Detailed Description of the Technology that will be used During the Course of the Study to Recruit Participants, Capture, Record, or Transmit Data***Please select which technology(ies) will be used in this study (check all that apply and answer the questions in the relevant required section.*  |
|  | **Technology Type**  | **Examples** | **If Yes, Answer the Required Questions** |
| YES [ ]  NO [ ]  | **Mobile technology** | *For example, iPhone, Android devices, iPods, tablets, or other wireless devices.* | Who does the mobile technology belong to? [ ]  **Sponsor provided device, not owned by UTEP**[ ]  **Study participant owned device**[ ]  **UTEP provided device** |
| YES [ ]  NO [ ]  | **Social Media** | *For example Facebook or Twitter* | Provide Link(s):      Purpose:       |
| YES [ ]  NO [ ]  | **Website survey, or similar tool** | *For example, QuestionPro survey, surveys on external websites* | Name of website survey, or similar tool you are using:      |
| YES [ ]  NO [ ]  | **Cloud based storage** | *Cloud storage is a cloud computing model in which data is stored on remote servers accessed from the internet, or “cloud.” Examples include Google Drive, iCloud, Microsoft OneDrive, etc. Note, see institutional policy for use of DropBox in research.*  | Identify:       |
| YES [ ]  NO [ ]  | **Wearable Technology** | *Examples of wearable biosensors include accelerometers, activity trackers, wireless heart rate monitors, pulse oximetry sensors, and glucose sensors.* | Name of the device:       |
| YES [ ]  NO [ ]  | **Phone, Video or Web Conferencing**  | *Examples include Zoom, Adobe Connect, Skype for Business, Facetime,etc.*  | Name of the conferencing system:      The recordings capture?[ ]  **Images**[ ]  **Audio**[ ]  **Video** |
| YES [ ]  NO [ ]  | **Text messaging/secure messaging**  | *Examples include Outlook, text, etc.* | What type of messaging will be used: [ ] **Text** [ ]  **Email** [ ] **Other**Purpose:       |
| YES [ ]  NO [ ]  | **Mobile Applications** | *Examples include those created by the PI, Apple health, Garmin connect, Fitbit, etc.* | Name of the application:       |

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| 1. **Sample:**

*Identify the sources of potential participants, derived materials, or data.* *Define the study sample (number of subjects to be enrolled, characteristics of subjects, inclusion and exclusion criteria).* ***Specifically define the procedures that will be used to recruit, screen, and follow study participants.*** *Please describe whether some or all of the participants are likely to be vulnerable to coercion or undue influence, and if so, what additional safeguards are included to protect their rights and welfare. Explain the rationale for the use of special classes of participants whose ability to give voluntary informed consent may be in question. Such participants include students in one’s class, people currently undergoing treatment for an illness or problem that is the topic of the research study, people who are cognitively impaired, and vulnerable populations.*  |

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| **Is there a possibility of coercion or undue influence?** YES [ ]  NO [ ]  |

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| 1. **Informed Consent:**

*The formal consent of each subject must be obtained before that subject is subjected to any study procedure. Describe how participants will be fully informed of this research prior to their participation and how their voluntary consent will be documented. If you anticipate enrolling subjects whose primary language is not English, how will you obtain informed consent in the language of those participants. Identify who will be involved in the consent process and where this will occur. If applying for a waiver of documented consent, specifically state this and provide justification. If the study involves deception, describe the procedures for debriefing the participants.*  |

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| 1. **Detailed Study Procedures:**

*Outline step-by-step what will happen in this study and to the human subjects. What will you ask your participants to do? When and where will they do it? How long will it take them to do it? Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect.* ***Identify the measurement/instrumentation.*** *For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project.* |

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|      **Will you be audio or video recording during any portion of this project?**YES [ ]  NO [ ] **IF yes, this information must be described in all pertinent sections and the ICF(s).** YES [ ]  NO [ ] **Will subjects be compensated (payment, incentives, extra credit, etc.)?****If yes, details should be included above.**YES [ ]  NO [ ]  |

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| 1. **Privacy and Confidentiality:**

*Describe how the project team will protect the privacy and confidentiality of study participants: Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information or data that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Note that ensuring privacy of participants is different from confidentiality of data.* |

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| 1. **Data Handling, Record Keeping, and Data Analysis:**

*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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| **Will you maintain a subject list that has direct identifiers linked to a unique study ID/code?**YES [ ]  NO [ ] **If yes, how will you secure the linking list?****Will UTEP study personnel electronically transmit identifiable data or identifiable samples to a non-UTEP recipient?**YES [ ]  NO [ ] **If yes, describe the type of data and the plans for secure transmission:****Indicate below what will happen to the identifiable data at the end of the study.**[ ]  Identifiers permanently removed from the data and destroyed[ ]  Recordings transcribed without identifiers and destroyed[ ]  Identifiable or coded (that can be linked) data are retained[ ]  N/A |
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| 1. **Risks:**

*Describe any* ***potential risks*** *(physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Describe alternative and potentially less risky methods, if any, that were considered as possible methods and why they were not used. If the research methods impose risks on the subjects, include evidence that may justify their use (such as previous experience with the procedures). Most studies pose some degree of risk, even though the risk may be minimal. For example, one common risk is the loss of the confidentiality of the participants’ responses. Describe the procedures for protecting against (or minimizing) any potential risks and include an assessment of their effectiveness. If the study involves a procedure that introduces a physical risk, specify arrangements for providing medical treatment if it should be needed. If the study involves a procedure that introduces a psychological risk, such as the recall of a traumatic event, specify arrangements for providing psychological treatment if it should be needed. Please state whether or not you will provide payment for physical or psychological harm if it is incurred.* |

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|      **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 [ ]   |

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| 1. **Benefits:**

*Describe and assess the* ***potential benefits*** *to be gained by participants (if any) and the benefits that may accrue to society in general as a result of the planned work. Discuss the risks in relation to the anticipated benefits to the participants and to society. Note, monetary compensation and extra credit are not a benefit.*  |

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| 1. **Research Resources:**

*Please describe your research resources. Discuss the staff, space, equipment, and time necessary to conduct research and how these needs are met. Please include a description of the proximity of any resources such as emergency facilities, emergency care or medical / psychological care, and any support services. If the study necessitates Environmental Health & Safety (EHS) or Institutional Biosafety Committee (IBC) oversight and approval please describe here.* |

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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).  |