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| --- |
| **Expedited request** **[ ]  OR Full request** **[ ]**  |
| Status: [ ]  Administrator | [ ] Faculty | [ ]  Graduate Student | [ ]  Staff | [ ]  Undergraduate |
| Principal Investigator (PI):       | *If PI is a student, complete this section:* |
| Title:       | Responsible Project Investigator (RPI)*(faculty/staff sponsor)*:       |
|  |  |
| Department:       | Department:       |
|  |  |
| Phone number: (   )    -     | Campus phone number: (   )    –     |
| E-mail:       | E-mail:       |
| For students only: Is this research being done to meet a course, thesis or other academic requirement? [ ]  Y [ ]  N |
| If yes, please specify:       |
| If not, why is it being done?       |
| Title of Project:       |
| Project anticipated start date:       | Anticipated termination date:       |
| Funding: [ ]  Non-funded [ ]  Internal funding [ ]  External funding |
| Funding agency (if applicable):       |
| Grant or Contract Number:       |
|  |
| Abstract:       |
|  |
| I certify that the information provided above is accurate and the project will be conducted in accordance with applicable Federal, State and university regulations: |
|  |
| PI Signature(s) *(unnecessary signature lines can be deleted)*:  |  |
|  |  |
|  |  |
|  |  |
| Submit this original, signed to the Institutional Review Board through e-mail to IRB@ewu.edu |
|  |
| **Recommendations and Action:** | **Date Approve/Disapprove** |
|  |
| RPI Signature *(Needed only if PI is a student)*: |  [ ]  A D [ ]  |
|  |
| IRB Rep. or Dept. Chair:*(Needed if PI is a student OR for faculty PI if required by department)* |  [ ]  A D [ ]  |
|  |
| IRB Signature:  |  [ ]  A D [ ]  |
|  |
| [ ]  Subject to the following conditions: Click or tap here to enter text.  |
|  |
| Period of approval: Click or tap to enter a date. to Click or tap to enter a date. |

**I. Research Protocol**

Please attach a summary (Attachment A), **two pages or less** in length, of the proposed research addressing each of the following points (A-E) separately. **Do not** submit any other document in place of this two page summary.

1. Background or rationale for this activity
2. Objectives of this specific research
3. Describe how subjects will be involved, specify what they will do. Attach (Attachment B) any cover letters, information statements, questionnaires or other formal instruments to be used in the research, describe procedures and/or protocol(s) for unstructured interviews, etc.
4. Explain how data obtained will answer the research problem
5. Identify alternative procedures, if any, that might be advantageous to the subject

**II. Human Subjects**

1. Number of subjects, including individuals who serve as “controls:”
	1. Approximate number not to be exceeded and ages:

|  |  |  |
| --- | --- | --- |
|  | Number | Age Range |
| Normal: |       |       |
| Vulnerable: |       |       |
| Control: |       |       |
| Total: |       |       |

1. Source(s) and type(s) of subjects:

1. Criteria for selection/exclusion of subjects:

1. How subjects will be approached and by whom:

1. Location where procedures are to be carried out:

**III. Voluntary Participation**

1. Describe the method for ensuring that subjects understand that their participation is voluntary and that they do not feel coerced:

1. Will subjects receive an inducement, e.g., payment, services without charge, extra course credit? Specify details. What is the rationale for offering the inducement?

1. If subjects are children and they are capable of assent, describe provisions for soliciting their assent as well as the provisions of soliciting permission of their parent(s) or authorized representative. If there is an assent form or standard briefing statement for children provide a copy as an attachment (Attachment C):

1. Attach a copy of the consent form to be signed by the subject and/or any explanations of the research to be given orally to the subject (Attachment D). If no consent form is to be used, explain the procedures to be used to ensure that participation is voluntary. (See instructions for required content of consent forms and safeguards for vulnerable populations.):

1. If any deception (withholding of complete information) is required for the validity of this activity, explain why this is necessary, and describe a debriefing plain and/or attach a debriefing statement (Attachment E):

**IV. Confidentiality and Anonymity**

1. Will participation be anonymous, that is, the investigator will have no way to identify subjects by appearance, name or data? If subjects will be anonymous, describe the procedure for data collection to insure that anonymity is maintained:

1. If data are collected which could be associated with individual subjects, describe the methods to be used to ensure the confidentiality of data obtained. (Confidentiality for data is required unless subjects give express written permission that their data may be identified.):

1. Who specifically will have access to some or all of the data? What provisions are there for control over access to documents and data?

1. How long will data with identifiers (both paper and electronic) be held? How will they be ultimately disposed of? If they will be retained more than five years please explain why this is necessary:

**V. Risks/Benefits**

1. Will subjects in the proposed research be placed at more than minimal risk, as defined by federal policy?

1. Nature and amount of risk (including side effects), substantial stress, discomfort, or invasion or privacy:

1. What steps are being taken to reduce the level of risk, including any follow-up planned as part of the risk mitigation procedures:

1. Plan for handling adverse effects:

1. Will this research be covered by any insurance policy? If yes, please explain the kind of coverage:

1. Describe the benefits to the subject and/or society of the proposed research. Why do the benefits outweigh any risks that may be involved?

**VI. Checklist** to be completed by investigator:

 Yes No

1. Will any group, agency or organization other than EWU be involved? [ ]  [ ]

If yes, please specify and attach letters of permission from other participating groups

1. Will materials with potential radiation risk be used, e.g., x-rays, radioisotopes? [ ]  [ ]

If yes, please indicate:

1. Status of annual review by Radiation Safety Officer (RSO):

If approved, attach one copy of approval (Attachment F)

1. Title of application submitted to Radiation Safety Committee (RSC):

1. Will any other hazardous materials come in contact with research subjects? [ ]  [ ]

If yes, indicate nature of hazard and steps taken to mitigate risk to subjects:

1. Will an investigational new drug (IND) be used? [ ]  [ ]

If yes, name, proposed dosage, how administered, status with FDA, and IND number:

|  |  |
| --- | --- |
| Name of new drug: |       |
| Proposed dosage: |       |
| How administered: |       |
| Status with FDA: |       |
| IND number: |       |

 Enclose one copy (Attachment G) of:

1. Available toxicity data
2. Reports of animal studies
3. Description of human studies done in other countries
4. A concise review of the literature prepared by the investigator.
5. Will other drugs be used? (including over the counter drugs) [ ]  [ ]

If yes, give names, dosages, how administered, and side effects:

|  |  |
| --- | --- |
| Names: |       |
| Dosages: |       |
| How administered: |       |
| Side effects: |       |
|  |  |

1. Will medical, academic or other records be used? [ ]  [ ]

If yes, please attach HIPAA or FERPA authorizations as appropriate

1. Will audio-visual or tape recordings or photographs be made? [ ]  [ ]

1. Should this activity be covered by adverse effects insurance? [ ]  [ ]

If yes, explain why:

1. Does the PI, RPI, or any other person responsible for the design, conduct, or reporting [ ]  [ ]

of this research have an economic interest in or act as an officer or director of any outside

entity whose financial interest would reasonably appear to be affected by the results of the study?

If **yes**, complete below:

Name of the person with potential conflict of interest (COI):

Explain the potential financial conflict of interest (FCOI):

Explain how the potential conflict of interest will be managed:

*(If the economic interest is a “significant economic interest” as defined in EWU’s* [*Summary of Conflict of Interest Policies*](https://inside.ewu.edu/ogrd/compliance/coi-summary-of-ewu-fcoi-policies/)*, submit the management plan established with the Conflict of Interest Committee.)*