

Principal Investigator's Name:

**East Central University
Institutional Review Board
Application for Initial Review**

IRB #: _____
Level of Review: _____

Statement by Researcher:

This form is designed for describing proposed programs of research which involve the use of human subjects and for reporting potential risks which may exist for those subjects. If any member of the Institutional Review Board Committee should require additional information, the investigator will be so notified. All documents should be submitted to the Office of Sponsored Programs & Research at Danley Hall (Room 226), and email an electronic copy to IRB@ecok.edu.

Date Submitted to the IRB: _____; **Proposed Project Period:** _____ to _____

Title of Study: _____

Principal Investigator (PI): _____; **Dept:** _____

PI Status: Faculty Student Staff; **Supervisor** (if PI is a student): _____

Address: _____; **Email address:** _____

Co-Investigator (if applicable): _____; **Dept:** _____

Study Contact Person: _____; **Phone:** _____

Sponsoring agency (if applicable): _____

Contract/Grant Number (if available): _____

Senior/Key Personnel*	Title/Role	Institution	Human Subject Education "Certification of Completion" Attached (Y/N)
	Principal Investigator		

*These investigators are required to complete IRB education and training prior to the submission of an IRB application. Senior/Key personnel include Principal Investigator, Co-PI, Supervisor, and other researchers who are significant contributors to the research.

Study Site	Federalwide Assurance # (FWA)**
East Central University 1100 E. 14th St, Ada, OK 74820	FWA00013984

**Federalwide Assurance # (FWA) and IRB approval are required for all non-ECU institutions.

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Project Summary: Briefly describe the proposed study, research design and procedures, and techniques to accomplish the stated goals. Describe the plans for monitoring and ensuring the protection of participants if the study involves more than minimal risk and/or harm.

ONE PAGE LIMIT

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Investigator's Risk/Benefit Assessment	
Investigator's Research Assessment (check one)	IRB Use Only – IRB Assessment
<input type="checkbox"/> Involves no more than minimal risk & benefit.	
<input type="checkbox"/> Involves greater than minimal risk & benefit.	
Describe any risks and/or harms associated with the study.	
<div style="border: 1px solid black; height: 60px;"></div>	
Describe the procedures to minimize the risks and/or harms and to protect the welfare of participants and others associated with the study.	
<div style="border: 1px solid black; height: 60px;"></div>	
Describe any anticipated benefits to research participants and others.	
<div style="border: 1px solid black; height: 60px;"></div>	
Do the benefits outweigh the risks and/or harms? Explain.	
<div style="border: 1px solid black; height: 60px;"></div>	

Existing Data (check all that apply)
<input type="checkbox"/> The research involves the use of existing data.
<input type="checkbox"/> Existing data is publicly available without fees or authorizations.
<input type="checkbox"/> The data set does not contain the participants' personal information.
<input type="checkbox"/> The data set contains the participants' personal information. If checked, please explain how their information will be protected.
<div style="border: 1px solid black; height: 60px;"></div>

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Research Population
Expected Number of Enrollment: _____; Age Range: _____
Sex: Number of Males: _____; Number of Females: _____
Inclusion Criteria: _____
Exclusion Criteria, if applicable: _____

Recruitment	
Methods of Recruitment (check all that apply)	% of Participants From this Method
<input type="checkbox"/> On-campus recruitment: East Central University	
<input type="checkbox"/> Off-campus recruitment: _____	
<input type="checkbox"/> Advertisement	
<input type="checkbox"/> Website: _____	
<input type="checkbox"/> Other: _____	

Special Enrollment	
Categories (check all that apply):	% of expected enrollment
<input type="checkbox"/> Children (under age of 18)	
<input type="checkbox"/> Pregnant Women	
<input type="checkbox"/> Prisoners	
<input type="checkbox"/> Mentally Impaired	

Waiver of Informed Consent Form	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the principal investigator requesting a waiver of informed consent for this study? If no, proceed to the next section. If yes, explain the reason for requesting the waiver below. <div style="border: 1px solid black; height: 150px; margin-top: 10px;"></div>

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Informed Consent	
<p>The consent form will be obtained from (check all that apply):</p> <p><input type="checkbox"/> Adult Participant</p> <p><input type="checkbox"/> Child Participant</p> <p><input type="checkbox"/> Parent/Guardian of Child Participant</p> <p><input type="checkbox"/> Legally Authorized Representative</p>	<p>If English is not the primary language in the consent process, state the language and who will be providing the verbal and written translation. Please attach the appropriate translated informed consent.</p> <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
<p>Describe the consenting process. State the duration between informing the prospective participants and obtaining the consent. How will the investigator provide potential participants with sufficient opportunity to consider participating in the study?</p> <div style="border: 1px solid black; height: 200px; width: 100%;"></div>	
<p>State and explain the reason(s) for any undue influence or coercion in obtaining subject's participation.</p> <div style="border: 1px solid black; height: 70px; width: 100%;"></div>	
<p>What steps will be taken to minimize undue influence or coercion in obtaining subject's participation?</p> <div style="border: 1px solid black; height: 70px; width: 100%;"></div>	
<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	<p>Will participants be offered compensation/inducements for participating? If yes, state below the form of compensation/inducements and how it will be handled if the participant withdraws from the study.</p> <div style="border: 1px solid black; height: 60px; width: 100%;"></div>

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Privacy and Confidentiality		
<input type="checkbox"/> Yes <input type="checkbox"/> No	Will others besides the research team be provided with a copy of the confidential research data? If yes, provide the name(s) to whom and reason(s) for the distribution below. <div style="border: 1px solid black; height: 40px; width: 100%;"></div>	
What are the actions taken to ensure confidentiality for all participants? <div style="border: 1px solid black; height: 80px; width: 100%;"></div>		
Data types (check all that apply)	Will the participants be identified? (check all that apply)	If yes, explain why they are necessary to the study.
<input type="checkbox"/> Audio data	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Video data	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Photographs	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Explain how the data will be stored/protected and discarded. <div style="border: 1px solid black; height: 60px; width: 100%;"></div>		
<input type="checkbox"/> Yes <input type="checkbox"/> No	Will the data be kept after the completion of the study? If yes, please justify the reason for the record retention. <div style="border: 1px solid black; height: 60px; width: 100%;"></div>	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Will direct identifiers be used? If yes, proceed to the following questions. If no, proceed to the next section. Direct identifiers are names, social security #s, addresses, telephone #s, etc.	
Explain why it is necessary to use direct identifiers. <div style="border: 1px solid black; height: 80px; width: 100%;"></div>		

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How long will the identifiers be kept? Describe what coding system will be used to protect the identity of these participants.	
<div style="border: 1px solid black; height: 60px;"></div>	
How will these identifiers be maintained and discarded after the study is complete?	
<div style="border: 1px solid black; height: 60px;"></div>	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Will there be a link between the study coding system to the direct identifiers after the data collection is complete? If yes, explain why this link is necessary and how long it will be kept.

Investigator's Statement

I, _____, as **Principal Investigator** acknowledge that I am responsible for reporting any unanticipated problems or proposed procedural modifications to the IRB prior to any human research activities.

I will renew this application annually with the IRB unless otherwise directed by the IRB Chairperson.

I acknowledge that the research being conducted is in compliance with ECU policies and the recommendation and guidance provided by the Institutional IRB.

I certify that I do not have a significant financial conflict of interest that could affect the design, conduct, or reporting of the research.

Signature of Principal Investigator Date

Signature of Supervising Faculty Date

Signature of Co-Investigator Date

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Check list

Please include all applicable forms:

- Hard Copy of the IRB Initial Review Application
- Electronic Copy of the IRB Initial Review Application
- Grant application, if Applicable
- Informed Consent Form, Signed or Unsigned
- Parent/Guardian Consent Form, if Applicable
- Child Assent Form, if Applicable
- Recruitment Materials, if Applicable
- Survey Instrument/Questionnaire
- Certificate of Completion for the "Protection of Human Research Protection" Educational Training (one (1) per faculty or staff)
- Student Human Training Certification Form, if Applicable