

APPLICATION FOR REVIEW OF HUMAN PARTICIPANTS RESEARCH

The following is designed to briefly introduce you to important considerations when answering each item. There is no one “correct” answer for each item, we are simply providing guidance for how to answer or address the issues raised in each item. Please email an IRB member for more information, or to answer any questions you have. Attach application to an email and email to jwarnick@atu.edu (be sure to save a copy of your application).

- Make sure you delete all red type explanations.
- NOTE: Anticipate no action on applications that do not meet the timeline as posted on the IRB web site

- **APPLICATION FOR REVIEW OF HUMAN PARTICIPANTS RESEARCH**

**Submit hard copy with signatures to the
Arkansas Tech University, IRB, Jason E. Warnick, Ph.D., Witherspoon Building, Room 350**

Email application as an attachment to jwarnick@atu.edu

Principal Investigator(s): *I acknowledge that this represents an accurate and complete description of my research.*

Name of Primary PI	Signature of PI	Date
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Additional Researchers' Names

	Division
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Mailing Address

()	
Telephone Number	Email address (Students email account)

Adviser (complete if PI is a student): I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human participants are properly protected.

Name of Adviser/Chair (typed)	Signature of Adviser/Chair	Date
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Adviser's Address	Adviser's Email address	() Telephone
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Title of Project goes here -- 10-15 words that briefly describe the work

PLEASE NOTE: All applications should be typewritten and edited prior to submission for review. If sufficient space is not provided below for a complete description of the proposed project, please use additional pages as necessary.

Summary of Purpose and Objectives
(“See attached protocol” is not acceptable)

Item 1 Describe the purpose of the research. (Research Question/Hypothesis)

Provide summary in space below.

The purpose should briefly explain the “reason for the study”—not the expected outcome. Examples: The purpose of this study is to investigate the relationship between..... Or, the purpose of this study is to investigate the factors related to.....

Item 2 Describe the participants of this study, including:

1) Population to be sampled

1) Population: describe those characteristics that are pertinent to the study: Mentally competent, adults receiving services for...; Adult students in the freshman English class; Full-time employees who work with juvenile offenders.

2) Sampling procedures

2) Sampling procedures need to include exactly how participants will be recruited.

a) how they will be found/selected: All clients currently in the XYZ program at the ABC Agency; Interested students in the English 101 classes; 10 of 50 employees at the ACME Human Service Agency selected using a table of random numbers.

b) How they will be invited to participate (check as many as apply):

- Mailed a survey
- E-mailed a survey or request
- Asked verbally, face-to-face, by researcher
- Phone solicitation by researcher
- Asked by caseworker, instructor, administrator (circle appropriate one)
- Other (please explain)

3) Projected date of data collection:

4) Number of participants expected to participate

4) Number: Approximate number you plan to participate.

5) Relationship to agency/school

5) Relationship: If an agency or school (other than LCSC) is involved, specify your relationship with the agency. Provide a letter of permission from the agency or school on their letterhead **AS AN APPENDIX** (this should be scanned in for electronic submission).

6) *How long the participants will be involved*

6) Length of involvement: Actual length of time they will be observed tested, questioned. Example: for 30 minutes to fill out consent forms and questionnaire; 30 minutes for pre-test and 30 minutes for post-test occurring 8 weeks apart; for 3 months , once a week, during class time beginning ----, ending ---.

7) *Any follow-up procedures planned.*

7) Follow-up: Only note if you intend to contact participants after an intervention sometime in the future (i.e., post tests).

8) *Include a copy of the script or other mechanisms to be used to solicit participants.*

Include what you will say as you approach potential participants BEFORE giving them the consent form. **Provide this as a word-by-word script or outline AS AN APPENDIX.** If there is nothing prior to the consent form (e.g., you mail them a consent form and survey), make that clear here.

Summary of Methodology and Procedures

(“See attached protocol” is not acceptable)

Item 3 *Describe each proposed condition, intervention, or manipulation of human participants or their environments. Include a copy of any questionnaires, tests, or other written instruments, instructions, scripts, etc., to be used AS AN APPENDIX.*

Specify if self-created or provide a citation for the source. Include documentation AS AN APPENDIX that you have purchased, or have permission to use, the materials.

Describe exactly what will be expected of the participants: Examples: fill out survey, questionnaire, inventory, or scale; take pre-test, participate in group for 8 weeks, take post-test; undergo physical examination, participate in set of exercises, fill out satisfaction scale.

Risks, Costs and Benefits

Item 4 *What risks to participants are most likely to be encountered (physical or psychological, etc.)?*

If there are no anticipated risks, state “Any risks are considered to be minimal or nonexistent.”. If there are minimal risks: list. (some stress, embarrassment, emotional distress OR rapid heart rate, exhaustion, stiffness). Refer to definition of “Minimal risk” in the IRB Guidelines document on the website.

Item 5 Will the participants encounter the possibility of stress or psychological, social, physical, or legal risks that are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?

Yes No *If Yes, please explain below.*

If no—do not explain.

If yes—explain.

Item 6 Will medical clearance be necessary for participants to participate because of tissue or blood sampling, administration of substances such as food or drugs, or physical exercise conditioning?

Yes No *If Yes, please explain how the clearance will be obtained.*

Item 7 Will the participants be deceived or misled in any way?

Yes No *If Yes, please explain below.*

This may be “NO” because you have explained your intentions in your procedures and your use of the data in the “informed consent”. If any deception or withholding of complete information is required, explain why, and explain if, how, when, and by whom participants will be debriefed.

Item 8 Will information be requested that participants might consider to be personal or sensitive?

Yes No *If Yes, please explain below.*

Typically this is a “YES” if you are asking them for or observing any of the participants’ personal characteristics, attitudes, beliefs, habits, etc.

Item 9 Will the participants be presented with materials that might be considered to be offensive, threatening, or degrading?

Yes No *If Yes, please explain below, including measures planned for intervention if problems occur.*

If “NO”—do not justify.

If “YES”—explain what participants might find offensive, threatening, or degrading and what you, as the researcher, will do if participant becomes distressed.

Item 10 What approach will you use to minimize risks?

This follows from Items 4-9. If there are no anticipated risks in Items 4-9, check here: ____ If there are any anticipated risks in Items 4-9, what will you do to minimize the occurrence of any psychological, social, physical, or legal risks presented in Items 4-9?

Item 11 What are the costs to the participants (monetary, time, etc.)?

Typically, time to fill out questionnaires, etc. (Example: 30 minutes). However, you need to consider the “cost” of participation in interventions, ie. Transportation, time off work, etc.

Item 12 Will any inducements be offered to the participants for their participation?

Yes No If Yes, please explain below.

Only explain if “yes”.

If extra course credit is offered, describe the alternative means for obtaining additional credit available to those students who do not wish to participate in the research project.

Item 13 Describe the benefits that might accrue to either the participants or society. Note that 45 CFR 46, Section 46.111(a)(2) requires that the risks to participants be reasonable in relation to the anticipated benefits. The investigator should specifically state the importance of the knowledge that reasonably may be expected to result from this research.

1) Participants: now or future.

2) Society (community) now or future.

Consenting Process

Item 14 Where will the research study be conducted (school, hospital, etc.)?

Actual site(s). List the names of agencies, schools, etc.

Item 15 How will the research study be explained to the participants?

Briefly explain whether it will be explained verbally (and by whom) or in written form and (how they will receive this form). This may be during recruitment, in the consent form, after consent or any combination.

Item 16 In what manner will you present the information for informed consent?

____ Oral ____ Written

Please include the consent/assent forms or format for oral consent.

A suggested format and checklist for the consent form (click this link for the [Consent Form Guideline](#)) may be useful as a guide. Elements of informed consent can be found in 45 CFR 46, Section 116.

Item 17 How will the consent form be explained to the participants? (Consider all barriers including culture and language.)

This is in addition to Item 15 that asks “how the research study” will be explained. Often times the study and request for consent happen at the same time, but not always. Do not include the consent form here, but whether this will be orally or written or both.

If there are any possible language barriers involved, state in detail how these will be addressed.

Explain: typical examples are non-English speaking participants, physically disabled (blind or hearing impaired), cognitively delayed or immature, etc.

Item 18 *How will you make it clear to the participants that their participation is voluntary and they may withdraw from the study at any time they wish to discontinue participation?*

Typically this is stated in the consent, however, there may be situations where it is explained more than once: when and why. Cut and paste the relevant statement **HERE**.

Data Collection

Item 19 *Who will have access to the raw/gathered data? (Investigator, staff, sponsor, LCSC IRB, FDA, etc.)?*

Typically: researcher/s, research advisor if student researcher, and whomever the researcher will share the information. Identify people by name and their relationship to the research.

Item 20 *Will the data be a part of a record that can be identified with the participant?*

Yes No

If Yes, please explain how you will protect the confidentiality of participants.

Typically, do not collect names (anonymous data collection); or remove names from data collected (specify when). You may also need to ensure that other identifying information is also deleted or “hidden” i.e., profession or job title if only one in agency.

Item 21 *What are the plans for retention of raw data?(Note: includes hard copy and raw data computer files)*

- 1) how will you secure the data for the duration of the research;
- 2) how long do you intend to keep raw data (Note: anonymous data can be kept forever)
- 3) how will the data be destroyed and at what point in time? (Typically, raw data is shredded or erased within five years, particularly if identifiers are attached.)

Item 22 *What are the plans for dissemination of results? (check all that apply)*

___ Presentation (paper or poster) at LCSC Research Symposium

___ Submission to Undergraduate Student Research Excellence Journal

___ Possible publication/conference presentation

___ Other (please explain)

Item 23 *If tissue samples or specimens are collected, when will they be destroyed? Will they be used for research other than what is described in the consent?*

Explain in detail.

Item 24 *Will the participant's participation in a specific experiment or study be made a part of any record available to his or her supervisor, teacher, or employer?*

Yes No *If Yes, please describe below.*

Explain if "yes".

THE IRB MUST APPROVE THE RESEARCH PROJECT *BEFORE* THE RESEARCHER(S) MAKE(S) ANY CONTACT WITH PARTICIPANTS.

CONTINUE BELOW BY CUTTING AND PASTING YOUR RESEARCH MATERIALS

Cut and paste approach script on this page...

Cut and paste survey or other research materials here (this can be more than one page)...

Checklist for application submission:

- Application (include grant proposal if funded project)
- Informed consent/assent forms
- Outline or script to be provided prior to participants' agreement to participate
- Instrument(s) [questionnaire, survey, testing]

Submit hard copy with signatures to:

Arkansas Tech University
Jason E. Warnick, Ph.D., IRB Chair
Witherspoon Building, Room 350
Russellville, Arkansas 72801

Email application as an attachment to: jwarnick@atu.edu

ANY CHANGES IN THE PROJECT AFTER APPROVAL BY THE IRB MUST BE RESUBMITTED AS A MODIFICATION FOR REVIEW BY THE IRB BEFORE APPROVAL IS GRANTED. MODIFICATIONS DO NOT CHANGE THE PERIOD OF INITIAL APPROVAL.

APPROVAL IS GRANTED FOR ONE-YEAR MAXIMUM AND MAY BE SUBJECT TO REVIEW AT ANY TIME THROUGHOUT THIS PERIOD. ANNUAL REQUESTS MUST BE MADE TO THE IRB FOR CONTINUATION, AS LONG AS THE RESEARCH CONTINUES.

REFERENCES TO 45CFR46 (Code of Federal Regulations) may be found at:

http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html