HUMAN SUBJECTS PROTOCOL SUBMISSION CHECKLIST

1. Cover Letter _____
2. Internal Proposal Application Cover Sheet _____
3. Endorsement Page
4. Reason for Study _____
5. Abstract* _____
6. Detailed Human Protocols _____
7. Survey Instruments Used in the Study* _____
8. Consent and/or Assent Forms*
9. Potential Risk Statement _____
10. Compensation Mechanism for Participants _____
11. Collaboration/Consultant Mechanism* _____
12. Letters from Consultants/Collaborators* _____
13. Steps Taken to Minimize Risk to Human Subjects* _____
14. Justification for Substantial Risk* _____
15. Methods of Obtaining Confidential Records* _____
16. Methods Used to Maintain Confidentiality* _____
17. Proof of a valid CITI certificate of the PI and any researcher (s) involved in the project (see details for CITI course below) ____

    Curriculum Group: Human Research
    Course Learner Group: Group 2. Social and behavioral research investigators staff and students.
    Stage 1 - Basic Course

Note: If not already completed, individuals conducting research involving human subjects are required to complete the *online* CITI Training Program within three months from the beginning of the project (www.citiprogram.org).
(See accompanying instructions at ***Office of Research and Sponsored Program, ORSP website)***

INSTRUCTIONS FOR SUBMITTING APPLICATIONS

All applications must follow the timeline outlined at the end of this document. Applications must be typewritten to the IRB Chair. Please email us your application under one combined pdf file. Applications must contain all the applicable features described in the Human Subjects Protocol Submission Checklist above.

Cover letter

This is a brief letter addressed to the IRB Chair which should include the title of the study, a brief description of how human subjects will be involved, the funding source for the study (if any) and the length of the study.

Internal Proposal Application Cover Sheet
This is the standard cover page used for all proposals on the University of Arkansas at Pine Bluff campus. It is found on the University website under Office of Research and Sponsored Programs. **All UAPB IRB applications which relate to new proposals must include this form effective from 3/3/25 per IRB Committee Agreement.**

Endorsement Page
On this page, please include the following information: 1) Name of investigator 2) Title of project 3) period of performance 4) date submitted 5) position and department of investigator 6) signature of investigator 7) e-mail address and telephone number of investigator 8) if the investigator is a student, faculty advisor's name.

Reason for Study

This is to be used for studies not being submitted for extramural funding at this time. This would include student projects or any projects that do not require funding at this time. The reason for the study should be described in one page or less. For faculty, reasons may include collection of preliminary data for proposals or assessment of teaching methods. Student projects should include the names and numbers of courses involved as well as the names of the instructors for these courses. **Studies which include a proposal cover sheet need not include this section.**

Abstract

This should be a 300 word or less synopsis of the study. **Studies which include a proposal cover sheet need not include this section.**

Detailed Human Protocols

This is a very thorough description of all experiments which involve human subjects. This must include a description of the subjects, their number and how they will be selected. This must include the location(s) at which the study will be conducted**. Letters of permission must be attached from each person responsible for the location at which the study will be conducted. Studies done at other academic institutions must acquire approval of the IRB on that campus.**

Survey Instruments Used in the Study

Copies of all survey instruments which one plans to use in the study must be included in the application.

Potential Risk Statement

The Human Subjects Committee (HSC)/Institutional Review Board (IRB) reviews the protocols to determine whether or not the study poses a **significant risk** to the participants involved in the study. Significant risk involves the potential of physical, emotional or reputational harm to the participants. If the PI feels that his or her research study carries a significant risk to the participants involved in the study, he or she must indicate so in the **Potential Risk Statement**

and address items 13 (Steps Taken to Minimize Risk to Human Subjects) and 14 (Justification for Substantial Risk) listed on checklist. Projects which carry significant risk will only be approved if evidence is presented indicating the benefits of the project outweigh the risks.

Collaborative Projects

In the case of collaborative projects, the details of the collaboration must be included. This would include names, titles and positions of collaborators, and a thorough description of their roles on the project. Letters of support from those collaborators must also be included. The above procedure is also required for consultants involved with the project. All work involving human subjects which is done on the UAPB campus must be approved by the university's HSC/IRB. If part of the project involves research involving human subjects performed at another institution, that work must also be approved by the HSC/IRB at that institution. Also, IRB must be notified concerning what steps have been taken to obtain IRB review at that institution.

PIs are also required to submit a signed copy of the Institutional Review Board (IRB) Authorization Agreement Form from collaborative institutions and CITI certificates of all researchers involved in the project. This form can be found at the ORSP website.

Health-Related Protocols
Health-related protocols would include studies which examine body fluids or tissues or involve exercise regimens or special diets. **In these cases, IRB requires that a licensed physician be included as a consultant.**

Confidential Records
Confidential records include medical records, employment records, police records, credit records and academic records. For all studies involving confidential records, IRB requires the PI to clearly indicate **how** these records will be obtained and comments on the **legality** of the methods used to obtain these records. Also, the method used to maintain confidentiality must be clearly described.

> Data Storage: PI must provide a statement on the location and duration of how long original data, or any identifiable information will be stored while maintaining confidentiality. As a standard practice following the minimum three-year retention period, individually identifiable information (including the master key and any combination of indirect identifiers that could reasonably identify a subject) must be destroyed, if it has not been already.

Studies Involving Survey Instruments
The major concern in studies of this nature is questions of a sensitive or potentially incriminating nature. Such questions would include questions related to sexual practices, drug or alcohol use, illegal practices, criminal records or credit history. In projects containing studies of this type**, the PI must submit copies of all survey instruments used in the study to IRB**. This applies to both written and oral surveys.

Compensation
The Human Subjects Committee requires that all human subjects involved in research studies be justly compensated for their time and effort on the project. The degree of compensation should be commensurate with the time and effort involved. The only exceptions would include projects involving a minimum of time and effort, and projects in which the participants receive a clear benefit from the study. **A description of the mechanism by which all human subjects involved in the project will be compensated must be included in the protocols.** If the PI feels that his or her project meets one of the criteria listed to waive compensation, he or she must submit a **justification statement** explaining why the project meets these criteria.

ONGOING PROJECTS

Periodic Review
Within one year after the beginning date of a project, each investigator must complete a **periodic review and protocol change form** which is available online on the UAPB website. This form must be approved by the IRB before the study can continue

Changes to Protocols

Any changes to an IRB-approved protocol must be further approved by the IRB. Before making changes to any approved protocol, investigators must submit a **periodic review and protocol change form** which must be approved by the IRB before the changes can go into effect. The form is available on the UAPB website.

Incident Reports

Any injuries, emotional disturbance or serious complaints among participants in the project which are directly related to the project must be promptly reported to the IRB. These incidents should be reported on an **incident report form** which is available on the UAPB website.

TYPES OF REVIEWS

An application submitted to the IRB may undergo one of three types of reviews, depending upon the nature of the project. These are:

1. **Full IRB Review**

Full IRB reviews are conducted when the IRB chair determines that the study presents significant risk to the participants. Full review involves the review of the study by the entire IRB committee and may require several days-months.

2. **Expedited Review**

An expedited review is conducted when the IRB chair determines that the study presents no significant risk to the participants. Expedited review involves the review of the study by the IRB chair only and may take less time.

3. Exemption Review

Certain studies are considered exempt from IRB review according to Federal guidelines. These include educational studies and assessment of programs and projects. Projects of these types must still be submitted to the IRB. However, after reviewing an exempt study, the IRB chair will notify the investigator that his or her study is exempt from review.

Approximate Timeline for IRB Review Process

The IRB meets during the first Monday of each month unless the University is closed due to holidays or weather.

Full Board Review

Only applications that require **Full Board Review** must be submitted by the **last Wednesday of every month.**

An application submitted on the last Wednesday of the month (excluding summer and holidays) will be reviewed by next month's meeting. **The IRB meets during the first Monday of each month** unless the University is closed due to holidays or weather. Thus, any application submitted for **Full Board Review** by the **last Wednesday of every month will be reviewed by the Committee during the first Monday of next month** (excluding summer and holidays)**. The committee does not meet over the summer/winter breaks/holidays.**

Approximate Timeline for Full Board Review: 1-2 months.

Please Note: Assignment to an agenda is **not automatic** and may vary depending on the completeness of the submission, complexity of the project, how quickly the researcher responds to comments during the pre-review and attaining quorum at the monthly meeting.

Expedited Review or **Exempt Review**

An investigator may request an **Expedited Review** or **Exempt Review** of their application if the proposed research activity falls within the category of **Expedited Review or Exempt Research** (see above descriptions in the document for each category). **Applications requesting Expedited Review or Exempt Review may be submitted at any time.** The IRB aims to review and send comments back to investigators within ten (10) working days.

Approximate Timeline for Expedited Review or **Exempt Review: 10 working days.**

Please Note: This does not mean that you will have IRB approval in ten days.

Please Note: Just because a study meets the exemption criteria does not mean that the IRB cannot review it or that ethical components like appropriate subject selection and consent are not important or unnecessary.

Principal Investigators (PIs) are advised to submit their applications well in advance of the proposed start date or the continuing review date of the study. The start date that PI will input into their online application must be reasonable and allow enough time for screening and IRB review. An exact IRB approval timeline cannot be provided as it will vary from one submission to another and may also vary due to periods of high submission volume.
IRB will not review or approve a study retroactively or approval for research studies that have already been conducted. IRB approval must be obtained before research activities begin, not after the research process has been completed.