## HUMAN SUBJECTS PROTOCOL SUBMISSION CHECKLIST

| | | |
|---|---|---|
| 1. | Cover Letter | ____ |
| 2. | Proposal Cover Page | ____ |
| 3. | Abstract | ____ |
| 4. | Detailed Human Protocols | ____ |
| 5. | Any Survey Instruments Used in the Study* | ____ |
| 6. | Potential Risk Statement | ____ |
| 7. | Compensation Mechanism for Participants | ____ |
| 8. | Collaboration/Consultant Mechanism* | ____ |
| 9. | Letters from Consultants/Collaborators* | ____ |
| 10. | Steps Taken to Minimize Risk to Human Subjects* | ____ |
| 11. | Justification for Substantial Risk* | ____ |
| 12. | Methods of Obtaining Confidential Records* | ____ |
| 13. | Methods Used to Maintain Confidentiality* | ____ |
| 14. | Proof of Completion of ***CITI Training in the Protection of Human Research Subjects*** | ____ |

*if applicable

***(See accompanying instructions.)***

**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).

**Submit to:** **Chairperson**
**Human Subjects Committee**
**Caine-Gilleland Hall, Suite 339, Rm. 337**
**University of Arkansas at Pine Bluff**

**Contact Person:** **Chairperson, Human Subjects Committee**

**Phone:** **575-8894**

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PRINT RESET

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 10 and 11 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, HSC/IRB must be notified concerning what steps have been taken to obtain HSC/IRB review at that institution.

## 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, HSC/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, HSC 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.

## 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 HSC/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.