THE UNIVERSITY OF ARIZONA HUMAN SUBJECTS PROTECTION PROGRAM
WORKSHEET FOR DETERMINING IF RESEARCH INVOLVING HUMAN SUBJECTS REQUIRE IRB REVIEW

PROJECT TITLE: ____________________________

IDENTIFICATION OF PI(S)
Principal Investigator(s) and Degree(s): ____________________________
Department: ____________________________

PURPOSE
The purpose of this form is to assist investigators in determining whether their project requires submission to the Human Subjects Protection Program (HSPP). The following is based on the Human Subject Regulations Decision Charts at http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm. If at any point the answers lead to the conclusion that the project constitutes research involving human subjects, then stop filling this form out and complete the appropriate HSPP initial application form. If this form indicates that the project does not constitute research involving human subjects, then:

1. Record comments as indicated to support the answer; and
2. Submit this form and requested supporting materials to the Department Head or comparable authority for review.
3. After completion, store the completed, signed form with the research project files.

CAUTION
It is against Federal regulations to conduct research involving human subjects without prior IRB approval. This form helps you determine whether your project meets the federal definition of research involving human subjects.

Projects that do not require submission to the Human Subjects Protection Program may still have other requirements.

- Projects involving Native Americans, including the use of existing information or specimens, require review and approval by the tribe(s) involved.
- Projects involving deceased persons and involve Protected Health Information may fall under HIPAA regulations. Contact the HIPAA Privacy Officer, Jeniece Poole at (520) 621-1465.

If you have any questions or are unsure how to answer these questions, please contact the HSPP office at (520) 626-6721 BEFORE beginning your research. Violating Federal regulations is a serious matter and may result in the suspension of your research and/or loss of federal funding.

Please note: if you determine that this does not require IRB review, such determination cannot for any reason be reversed or revoked at a later date for any part of the project.

WORKSHEET

1. Is this project a systematic investigation designed to develop or contribute to generalizable knowledge (including use for a thesis or dissertation, publication or poster presentation)?
   If NO, the project is not considered research; IRB review is not required. Stop here.
   If YES, go to question 2.
   Comments/Rationale: ____________________________

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2. Does the research involve obtaining information about living individuals (this category includes secondary data analyses of existing data that was not obtained by the investigator of the proposed project)?
   - **If NO**, the project is not considered human subjects research; IRB review is not required. Stop here.
   - **If YES**, go to question 3.

   **Comments/Rationale:**

3. Does the research involve intervention or interaction with individuals **OR** is the information individually identifiable where the identity of the subject can be readily ascertained (e.g. through use of a unique identifier/code or use of any of the 18 elements of HIPAA that constitutes an identifier – name, age over 89, elements of dates including birth date or dates of service, medical record number)?
   - **If NO**, the project is not considered human subjects research; IRB review is not required.
   - **If YES**, complete and submit an IRB application to the HSPP office. Note that the project still may not require IRB review; however, this determination should be made within the HSPP office.

   **Comments/Rationale:**

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**ASSURANCES**

1. **PRINCIPAL INVESTIGATOR**
   By signing below, I, the Principal Investigator, certify that I have accurately answered the items listed and believe that the research project does not constitute human subjects research in accordance with DHHS regulations.

   ___________________________________  _____________  _____________
   Principal Investigator Signature         Date           Department

   ___________________________________  _____________  _____________
   Advisor Signature                       Date           Department

2. **DEPARTMENT HEAD**
   Based on the information provided by the Principal Investigator, I have determined that this project does not constitute human subjects research.

   ___________________________________  __________________
   Head of Department, College Dean or comparable authority (Signature)  Print Name

   ___________________________________  _____________
   Title                                    Date