# The University of Tulsa –Institutional Review Board Is this Human Subjects Research?

An activity must meet two federal definitions, "Research" and "Human Subjects", in order for the activity to be determined "Human Subjects Research".

All human subjects research, regardless of sponsorship MUST be reviewed and approved by The University of Tulsa Institutional Review Board (TU IRB).

## **QUESTION 1: IS THE ACTIVITY "RESEARCH"?**

- A.) The activity is a systematic investigation, including research development and testing. YES NO
- B.) The activity is designed or intended to develop or contribute to generalizable knowledge. YES NO

### If you answered NO to one or both of questions 1A. or 1.B, the activity is NOT "research". \*YOU CAN STOP THIS CHECKLIST, THIS CANNOT BE "HUMAN SUBJECTS RESEARCH".

If you answered YES to BOTH questions 1A. AND 1B., the activity is "RESEARCH". GO TO QUESTION 2

# **QUESTION 2: DOES THE ACTIVITY INVOLVE HUMAN SUBJECTS?**

- A.) Is the information being collected for the study personally about the individual they are collecting it from? YES NO
- B.) Does the investigator conducting research: (i) Obtain information or biospecimens through intervention or interaction with the individual, and use, study or analyze the information or biospecimens?; or (ii) Obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens?
  YES NO

#### If you answered NO to one or both of questions 2A. or 2B., the activity is NOT "human subjects". \*YOU CAN STOP THIS CHECKLIST, THIS CANNOT BE "HUMAN SUBJECTS RESEARCH".

If you answered YES to BOTH questions 2A. AND 2B. questions, the activity is , "HUMAN SUBJECTS".

If you answered YES TO BOTH questions in Question 1 AND Question 2, the activity is, "HUMAN SUBJECTS RESEARCH".

### IF YOUR ACTIVITY MEETS THE DEFINITIONS OF BOTH "RESEARCH" AND "HUMAN SUBJECTS" THAN YOUR ACTIVITY IS HUMAN SUBJECTS RESEARCH AND YOU ARE REQUIRED TO SUBMIT A PROTOCOL TO THE TU IRB OFFICE.

\*If you are still not sure that your activity meets one or both of the above federal definitions, please contact the TU IRB office.

Contact: researchcompliance@utulsa.edu, (918)-631-3310