

## WORKSHEET 301 – IS MY PROJECT “HUMAN SUBJECTS RESEARCH”?

### 1. Section I

a. Is my project “Research”?

Yes (Proceed to Section 2)

- i. Is my project a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?
- ii. My research project has a protocol or plan (includes needs assessment, testing, evaluation)
- iii. I plan to publish and/or present the findings from my research (including Masters Thesis/Dissertation) to a journal or national conference.

b. Following are specific activities (that may meet the criteria above) that are **not** research:

- i. Class projects intended primarily for training on research methods and practice.
- ii. Scholarly and journalistic activities such as: Oral History, Journalism, Biography, Literary criticism, Legal research, Historical scholarship.
- iii. Public health surveillance activities conducted by or ordered by a public health authority. This exception is limited to activities necessary to allow a public health authority to identify, monitor or investigate potential public health signals, disease outbreaks, or conditions of public health importance.
- iv. Collection and analysis of information, specimens or records by or for a criminal justice agency, for activities authorized by a law or court, solely for criminal justice or criminal investigative purposes.
- v. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

### 2. Section II

a. Does my research involve “Human Subjects”?

Yes

- i. My research project involves living individual(s) about whom I will obtain information or biospecimens through intervention or interaction with these individuals; or
- ii. My research involves living individual(s) about whom I will obtain, use, study, analyze, or generate identifiable private information OR identifiable biospecimens. This includes accessing private information or identifiable biospecimens from which individuals can be identified directly or indirectly through a link or code.

If your research activities do not fall under the criteria for both “Research” and “Human Subjects”, no IRB application is needed.