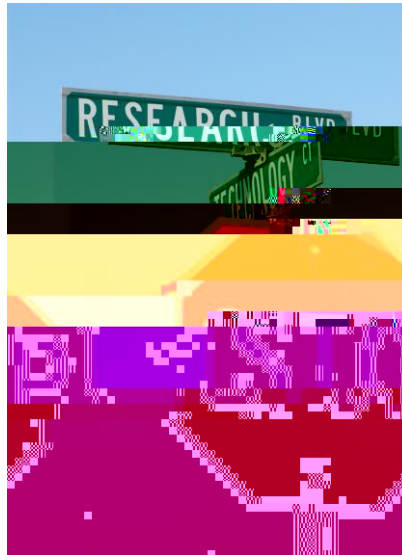


A Guide for Investigators



This guidance, prepared by the Office for the Protection of Research Subjects (OPRS) at University of Southern California (USC), has been modified by Saint Louis University's Institutional Review Board with permission. This booklet provides guidance to SLU investigators who may be uncertain if their study meets the definitions of human subjects research as stated in the federal regulations (45CFR46.102). The SLU IRB recognizes that the definition may not always provide a straightforward answer. *Is Your Project Human Subjects Research? A Guide for Investigators* offers investigators an explanation of the definitions as well as examples of studies that do or do not qualify as human subjects research. For further information, please refer to the *Resources* section in the back of this booklet.



- a human subject research project requires the data received from the living individual to be _____ the person.

includes physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," (such as a public restroom) " and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will _____ observation



-
1. Studies that involve human subjects for testing new devices, products, drugs, or materials.
 2. Studies that collect data through intervention or interaction with individuals. ExampET3 wit3 10.56 Tf1 0 0 1 15

3556 Caroline, Room C110
St. Louis, MO 63104
Phone (314)-977-7744
Fax (314) 977-7730
irb@slu.edu