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A Guide for Investigators

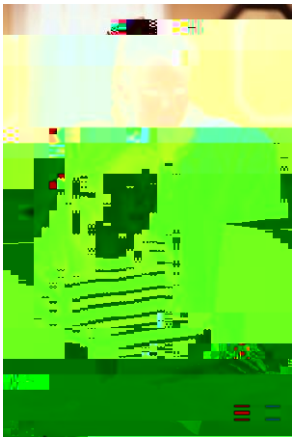
This guidance, prepared by the Office for the Protection of Research Subjects (OPRS) at University of Southern California (USC), has been modified by Saint Louis University's Institutional Review Board with permission. This booklet provides guidance to SLU investigators who may be uncertain if their 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 A bservation



individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

9. which are published and/or presented at national or regional meetings are considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge. SLU IRB policy states that 5 cases may be studied before submitting to the IRB.

10. , including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority are not considered research. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

11. by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

12. (as determined by each agency) in support of intelligence,

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

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