Table of Contents: What Needs IRB Review – Determination of Human Subjects Research

Any UIW employee or agent who engages in human subjects research under a UIW appointment or affiliation is required to follow UIW policies governing human subjects research. This includes obtaining UIW IRB approval or exemption prior to beginning any research activities involving human subjects unless the UIW IRB cedes IRB oversight to another institution.

For the purposes of this policy, the following definitions apply:

Agent:

on engagement of human subjects for tl

Interaction: includes communication or interpersonal contact between investigator and subject.

Private information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information: private information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Human Subject (FDA): an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)]. In addition, a human subject includes an individual on whose specimen an investigational device or control is used, even if the specimen is anonymous [21 CFR 812.3(p)].

Research: a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(l)]. Includes clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs, medical devices, biological products, or electronic products for human use (i.e., test articles). [21 CFR 56.102]

Note: The terms “systematic investigation” an/MCID 131.Tc 0 Tw 0CID 18 Ɔ460.8 Tm(e)-3 (sg 0.004 T0 -1.2R)-6.221.3 (c)-

- research studies using private information or biological specimens where the investigators can readily ascertain the identity of the individual to whom the information or specimens pertain; and/or

- pilot or feasibility projects that will be used to develop or evaluate research procedures for a

Antonio Metropolitan Health District, the Texas Department of State Health Services, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration) [45 CFR 46.102(l)];

- collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes [45 CFR 46.102(l)]; and/or

- a3006.6 Tw (300r (i)7hinMC /a6.6 TwionMC)2.3s

August 24, 2020

HHS Guidance on Engagement of Institutions in Human Subjects Research
45 CFR 46
21 CFR 56
21 CFR 812
Human Subjects Research Determination Questionnaire
IRB Guidance on Student Class Projects
IRB Guidance on Quality Improvement/Quality Assurance Projects
IRB Guidance on Secondary Data Analysis