This is an image that displays two equations for determining if IRB review is required under either the DHHS or FDA regulations. The first equation is for the DHHS regulations. It reads: RESEARCH plus HUMAN SUBJECT equals IRB REVIEW REQUIRED UNDER DHHS REGULATIONS. The equation also supplies the definitions of “Research” and “Human Subject” under the DHHS regulations.

“Research” is defined as “A systematic investigation designed to develop or contribute to generalizable knowledge.”

“Human Subject” is defined as “A living individual about whom an investigator either obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyze the information or biospecimens, AND/OR obtains, uses, studies, analyzes or generates identifiable private information or biospecimens.”

The second equation is for the FDA regulations. It reads: CLINICAL INVESTIGATION plus HUMAN SUBJECT equals IRB REVIEW REQUIRED UNDER FDA REGULATIONS. The equation also supplies the definitions of “Clinical Investigation” and “Human Subject” under the FDA regulations.

“Clinical Investigation” is defined as “Any experiment that involves one or more human subjects, AND an FDA-regulated test article (drug, biological product, medical device, human food additive, color additive, electronic product, or any other article), AND the results must (or may in the future) be submitted to the FDA as part of an application for a research or marketing permit.”

“Human Subject” is defined as “An individual who is or becomes a participant in research, either as a recipient of the test article or as a control.”