Purpose of the Policy:
Define when activities are deemed research involves human subjects.

Policy:
All activities meeting the definition of research, irrespective of funding, must be proposed to the IRB. RSPP staff then uses the following definitions to determine if review is required.

Research means “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Human participant means “a living individual about whom an investigator (whether professional or student) conducting research obtains either:

- Data through intervention or interaction with the individual, or
- Identifiable private information.” Including: a) using records gathered on human subjects, or b) involving human tissue.

For purposes of the FDA oversight:
Clinical investigation means any experiment that involves a test article and one or more human participants and that is one of the following:

- Subject to requirements for prior submission to the FDA under 505(i) or 520(g) or the act.
- Not subject to requirements for prior submission to the Food and Drug Administration.

Human participant means “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.” A participant may be either a healthy human or a patient.

Test article means “any drug, biological product, medical device, food additive, color additive, electronic product for human use.”