**Is the Activity Research Involving Human Subjects?**

**Question 1:** Is the activity research, i.e. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?

**Question 2:** Does the research involve human subjects, e.g. Does the research involve obtaining information or biospecimens about living individuals?

**Question 3:** Does the research involve obtaining information or biospecimens through intervention or interaction with the individual for use, study or analysis?

**Activity is research involving human subjects that is covered by the regulations.**

**Question 4:** Does the research involve obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens?

**Question 5:** Could the human subject research be eligible for an exemption from IRB review under the revised Common Rule? Review the criteria under the exemption categories.

**STOP. The activity is not research.** No IRB review or determination is required.

**STOP. The activity is not human subject research.** No IRB review or determination is required.

**STOP. The activity is not human subjects research.** No IRB review or determination is required.