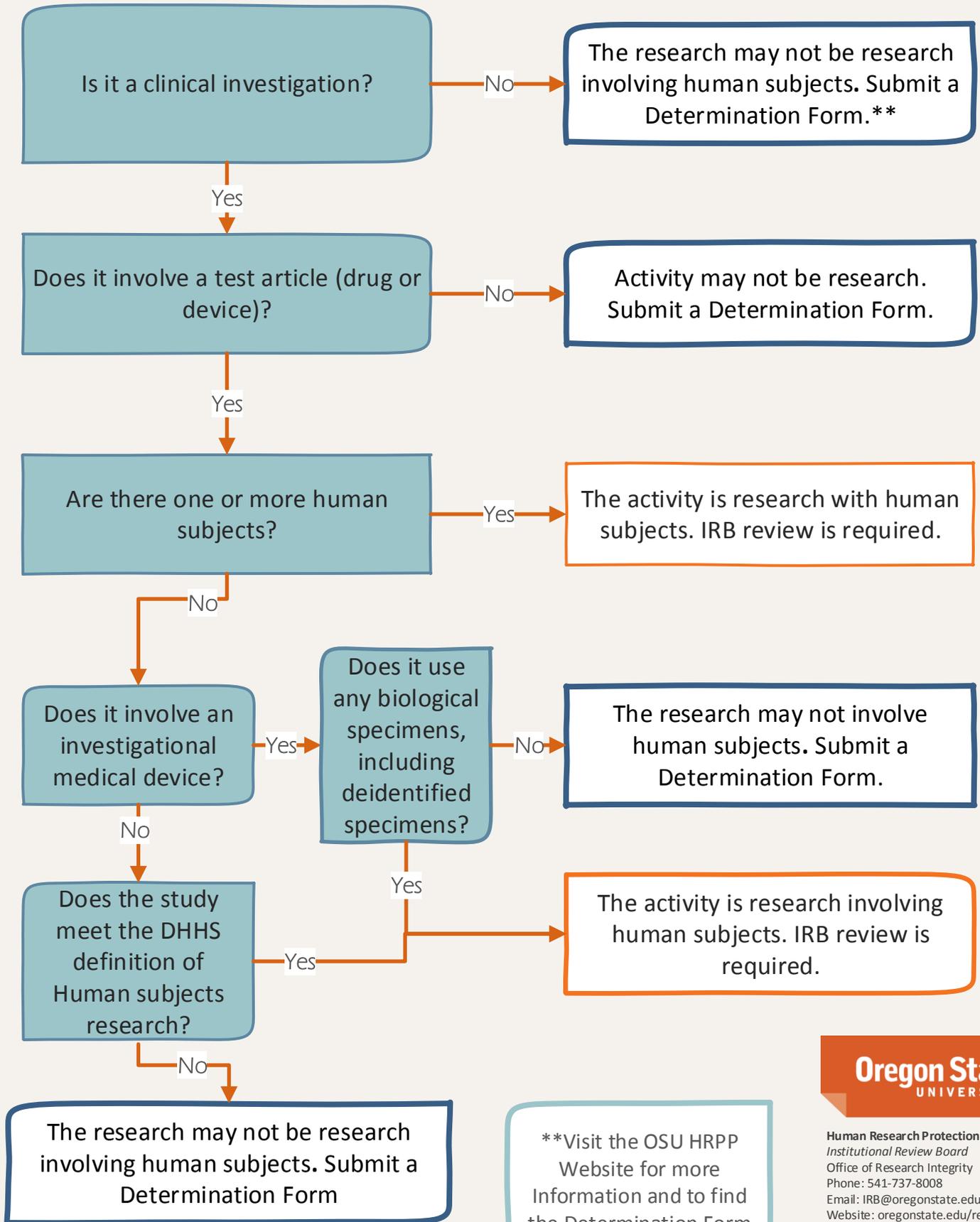


Is IRB Review Required under the FDA Regulations?



*See Below for Glossary

**Visit the OSU HRPP Website for more Information and to find the Determination Form



Human Research Protection Program
Institutional Review Board
Office of Research Integrity
Phone: 541-737-8008
Email: IRB@oregonstate.edu
Website: oregonstate.edu/research/irb

Glossary

Clinical Investigation: Clinical investigation means any experiment that involves a test article and one or more human subjects.

Test Article: Test article means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drugs, and Cosmetic Act (FD&C Act) or by the FDA.

Drug: The term "drug" means (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in the FD&C Act.

Medical Device: A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: (a) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Investigational device: A device, including a transitional device, which is the object of a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

Biological Specimen: A sample, as of human tissue, blood or urine, used for diagnostic or pathological analyses.

Please see [“Does my study require IRB review”](#) on the OSU HRPP Website for additional information about the DHHS definition of Human Subjects Research.