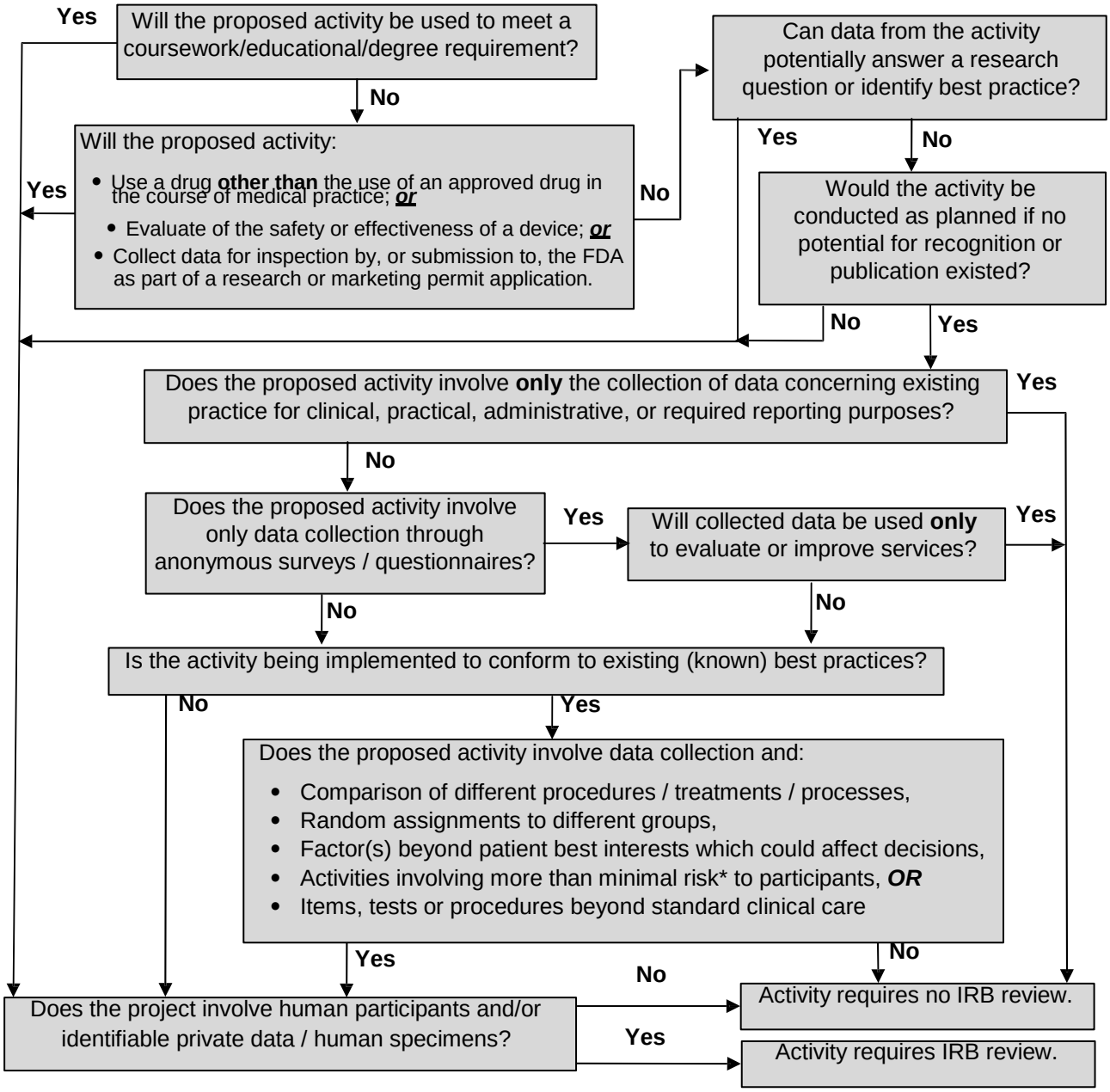
Texas Health Resources®

Institutional Review Board

DOES MY PROPOSED ACTIVITY REQUIRE IRB REVIEW?

Use this chart to determine whether a quality / performance improvement activity requires IRB review



Key Definitions

1. **Minimal Risk**: The probability and magnitude of harm or discomfort anticipated from the research activities are no greater risk than ordinarily encountered by a normal person in daily life or during routine physical or psychological examinations or tests
2. **Device**: An article and its parts/accessories intended for medical use which is NOT intended to affect the structure or function of the body through chemical action within or on the body. It is not dependent on being metabolized within the body to achieve its primary purpose, i.e. anything intended for medical use that is not a drug or a biologic. Also, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article.
3. **Human Subject**: A living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information. (OHRP) Also, an individual who is or becomes a participant in research, either as the recipient of the test article or as a control.
4. **Identifiable Private Data**: Private data 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 (for example, a medical record). Identifiable means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
5. **Human Specimens**: Biological samples obtained from a human donor, including, tissue, blood, saliva, urine, cells, and other body fluid.

Source: NIH Office of Extramural Research, HHS Office of Human Research Protections, THR Corporate Policy for Protection of Research Subjects