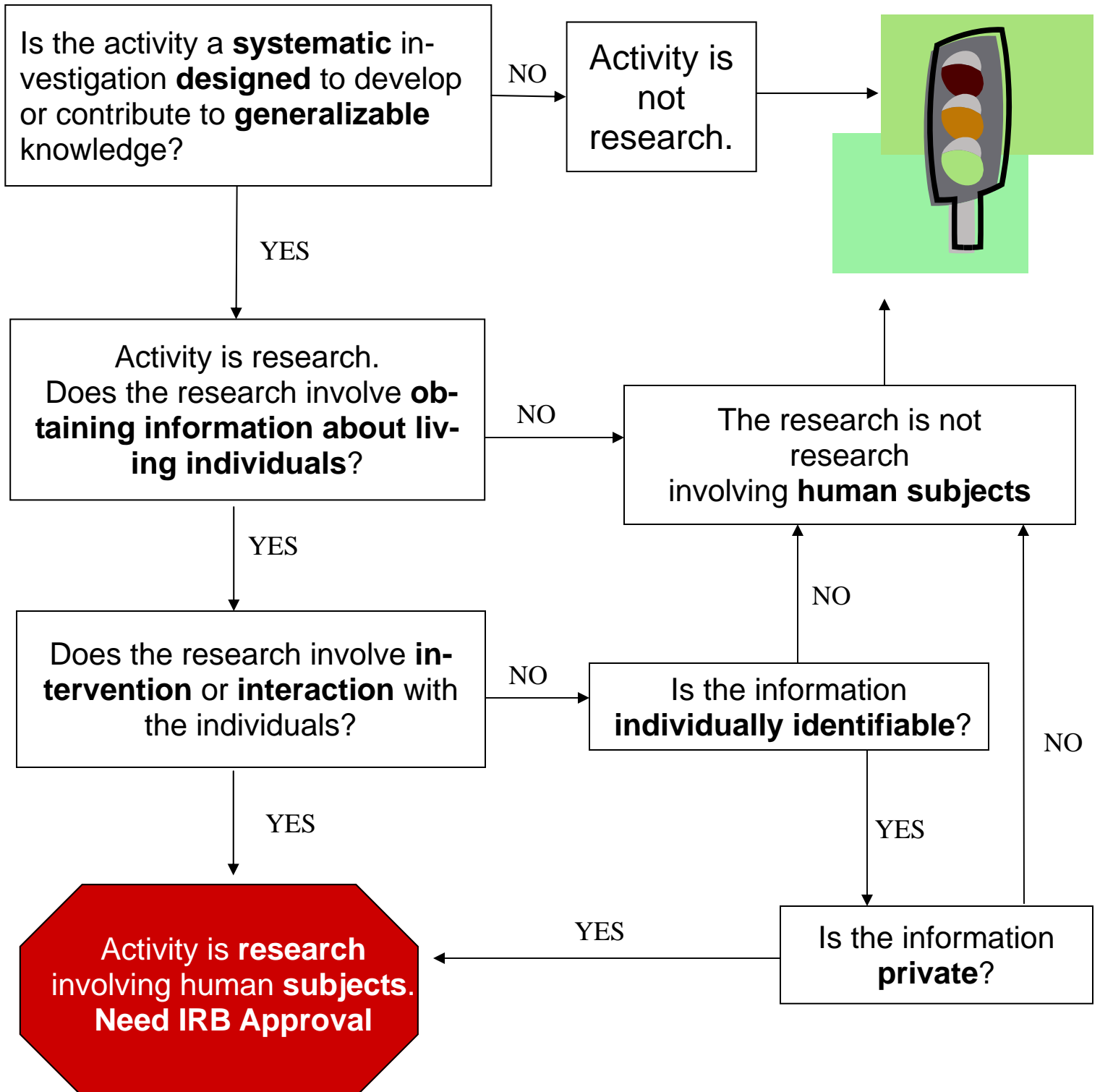


# Does my activity need IRB approval?



This decision tree is a simplified version of the one available on the HHS/OHRB website: “Is an activity research involving human subjects covered by 45 CFR part 46?” The full decision tree is available at <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>

# Definitions

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

Human subjects are living individuals about whom an investigator conducting research obtains *either* data through intervention or interaction with the individual or *identifiable* private information

Intervention includes both *physical procedures* by which data are gathered (such as blood draw) and *manipulations* of the subject or subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between researcher and subject

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It also includes information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (such as a medical record).

\*If the private information is not *individually identifiable*, the research does not constitute research involving human subjects.

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## An Example:

### Let's say you are researching paper towels...

You want to call every manager in all Hannaford stores in Maine and collect information about the brands available in their stores...

Do you need IRB approval? **NO**

**WHY?** Collecting information about the types of products a business sells is **not information about an individual** (and therefore it is not research involving human subjects).

### What if you ask those same managers what brand of paper towel they prefer to use at home...

Do you need IRB approval? **YES**

**WHY?** You're asking them for their opinion about something. You've **obtained information about an individual** (and therefore it fits the definition of research involving human subjects).  
Note: Existing data about an individual (educational, personnel or medical records) constitutes information about an individual as well.