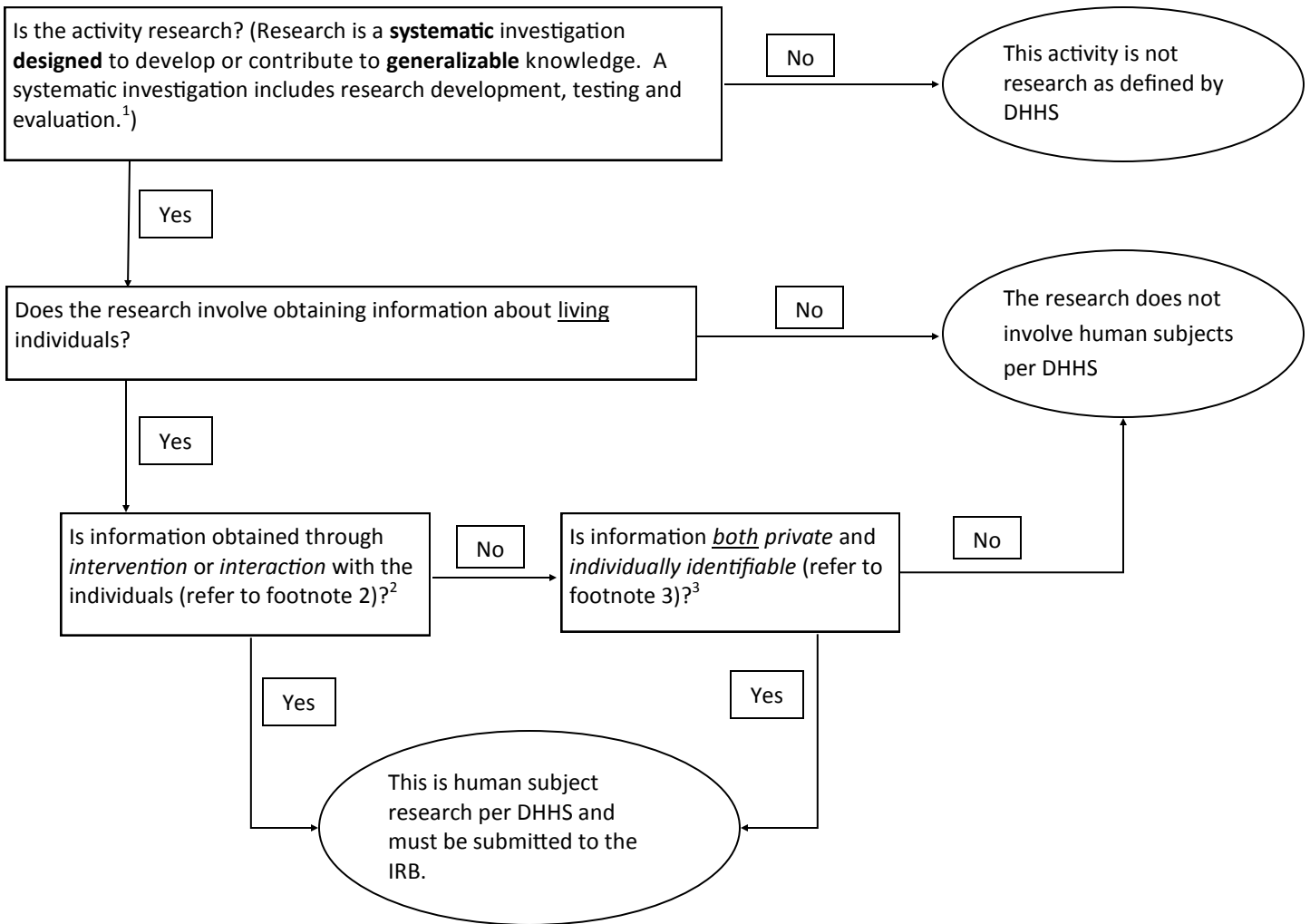


## Research / Not Research According to DHHS Regulations



1. As defined by DHHS 45 CFR 46.102(d), “Research” means a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge. When evaluating your project, focus on the following two key elements: (a) the project involves a systematic investigation, and (b) the design—meaning the goal, purpose or intent—of the investigation is to develop or contribute to generalizable knowledge. Having only one of these properties means that the activity is not “research” and should not be submitted to the IRB.
2. Intervention includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.
3. 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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example a medical record). Individually identifiable information indicates that the identity of the participant is or may be ascertained by the investigator or associated with the information.