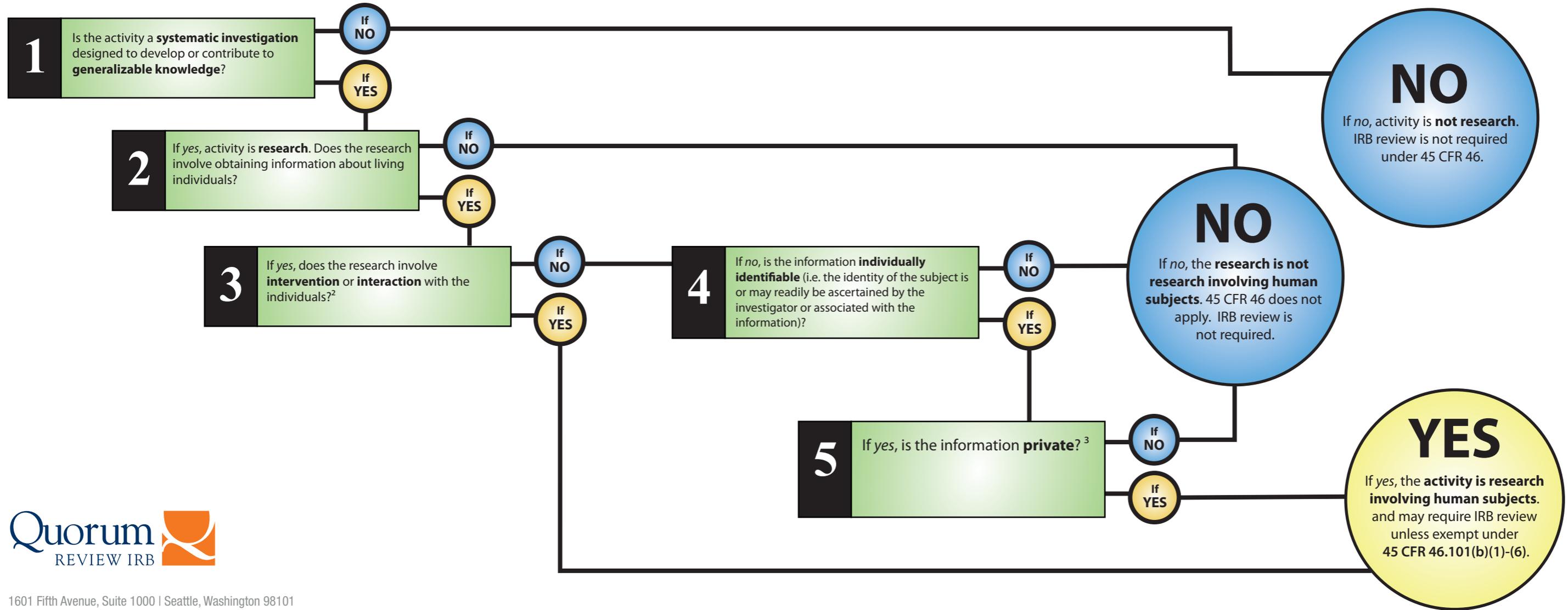


Quorum REVIEW IRB

When Performance Matters

Is an Activity defined as “Research Involving Human Subjects” under 45 CFR 46?¹



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¹Adapted from OHRP Human Subject Regulation Decision Charts, Chart 1, *Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?* September 24, 2004, available at: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1>.

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. (45 CFR 46.102(f))

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). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (45 CFR 46.102(f))