Does the protocol describe exposing humans to a drug?

Is the drug FDA approved and marketed?

IS NO

Is the drug used according to its FDA labeled indications?

YES NO

Does the study request a waiver of consent?

NO YES

If the use of the drug involves a route of administration, dose, or subject population that is not FDA approved, does this use increase subject risks or decrease the acceptability of risks?

NO YES

IND regs do not apply

IND regs apply; study is FDA-regulated

Investigator must apply to FDA to obtain an IND.

Dietary supplements do not require an IND if studied for effects on structure/function of the body.

Will research data be submitted to the FDA in support of a marketing application, or is the research intended to alter the labeling of the drug?

NO YES