Does activity involve any use of a drug other than the use of a marketed drug in the course of medical practice? [21 CFR 312.2]

No

Does activity involve determining the safety or effectiveness of a device?

No

Are the results of the activity intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit?

No

Activity is NOT "research" as defined by FDA.

Yes

Yes

Activity is "research" as defined by FDA.

Does the activity involve any individuals on whose specimen a medical device will be used?

No

Does the activity involve any individuals who will receive the test article or be used as a control?

No

Does the activity involve any individuals who will receive the test article or be used as a control?

No

Activity is NOT "research involving human subjects" as defined by FDA.

Yes

Does the activity involve any individuals who will receive the test article or be used as a control?

No

Yes

Activity is NOT "research involving human subjects" as defined by FDA.

Yes

Activity is "research involving human subjects" as defined by FDA.