Is this activity a systematic investigation designed to develop or contribute to generalizable knowledge?

Yes

Is this investigation gathering data about living individuals either through interaction or intervention or identifiable private information or biospecimens?

Yes

This activity is human subject research = do submit to IRB.

No

This investigation does not meet the DHHS criterion for research.

No

This investigation does not meet the DHHS criteria for human subject.

No

HOW TO DECIDE IF YOU SHOULD SUBMIT YOUR PROJECT TO THE IRB

• **Quality improvement or assurance activity** – systematic investigation designed to develop or contribute to organizational (rather than generalizable) knowledge
• **Program evaluation** - systematic investigation designed to develop or contribute to knowledge about the effectiveness of implementing a specific program
• **Generalizable** - universally or widely applicable
• **Private information** – occurs in the context in which an individual can reasonably expect that no observation or recording is taking place and data which is provided for a specific purpose that the individual can reasonably expect will not be made public
• **Private identifiable information** – the individual’s identity is or may be readily ascertained by the investigator or associated with the information or biospecimens