Is the NIH Researcher Conducting Human Subjects Research Requiring IRB Approval or an Exemption?

An individual is considered to be conducting human subjects research when for research purposes, he or she, e.g.:
- Obtains consent from subjects;
- Interacts or intervenes with subjects; or
- Conducts activities with identifiable data or specimens. Note: Coded data or specimens are considered identifiable, if the investigator or any member of the research team has access to the code key.

Activity is NOT research involving human subjects; No submission for human subjects protections review is required; Other NIH policies may apply

Activity is research involving human subjects; Submit a protocol to the IRB for review or consideration for an IRB exemption