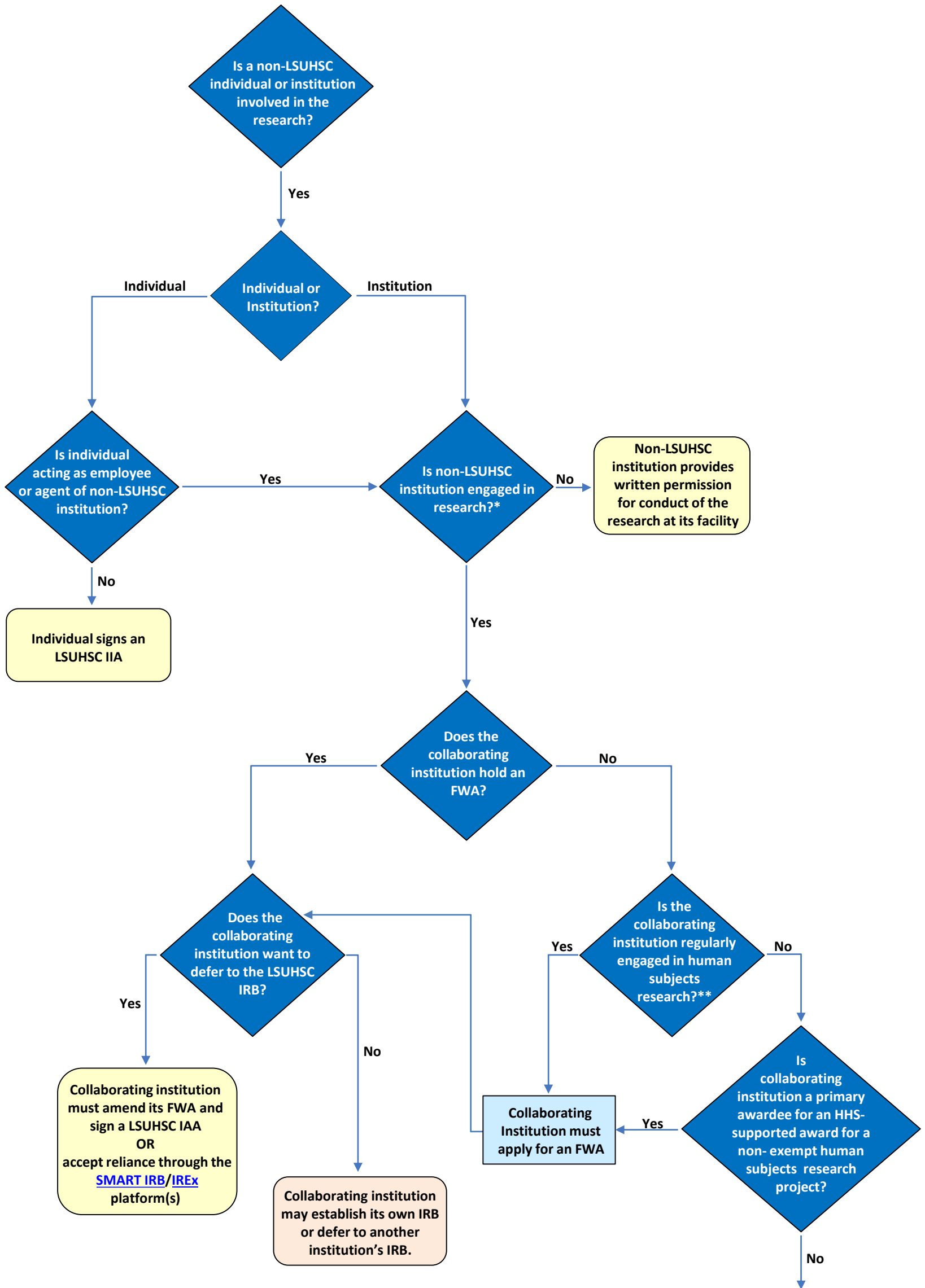


When is an IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA) Necessary?



*An institution becomes “engaged” in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

** An institution is considered “regularly engaged in research” if HHS-conducted or -supported human subjects research activity routinely occurs at the institution. (See <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>)

Collaborating institution's engaged researcher signs an IIA. Collaborating institution provides written permission for the conduct of the research at its facility