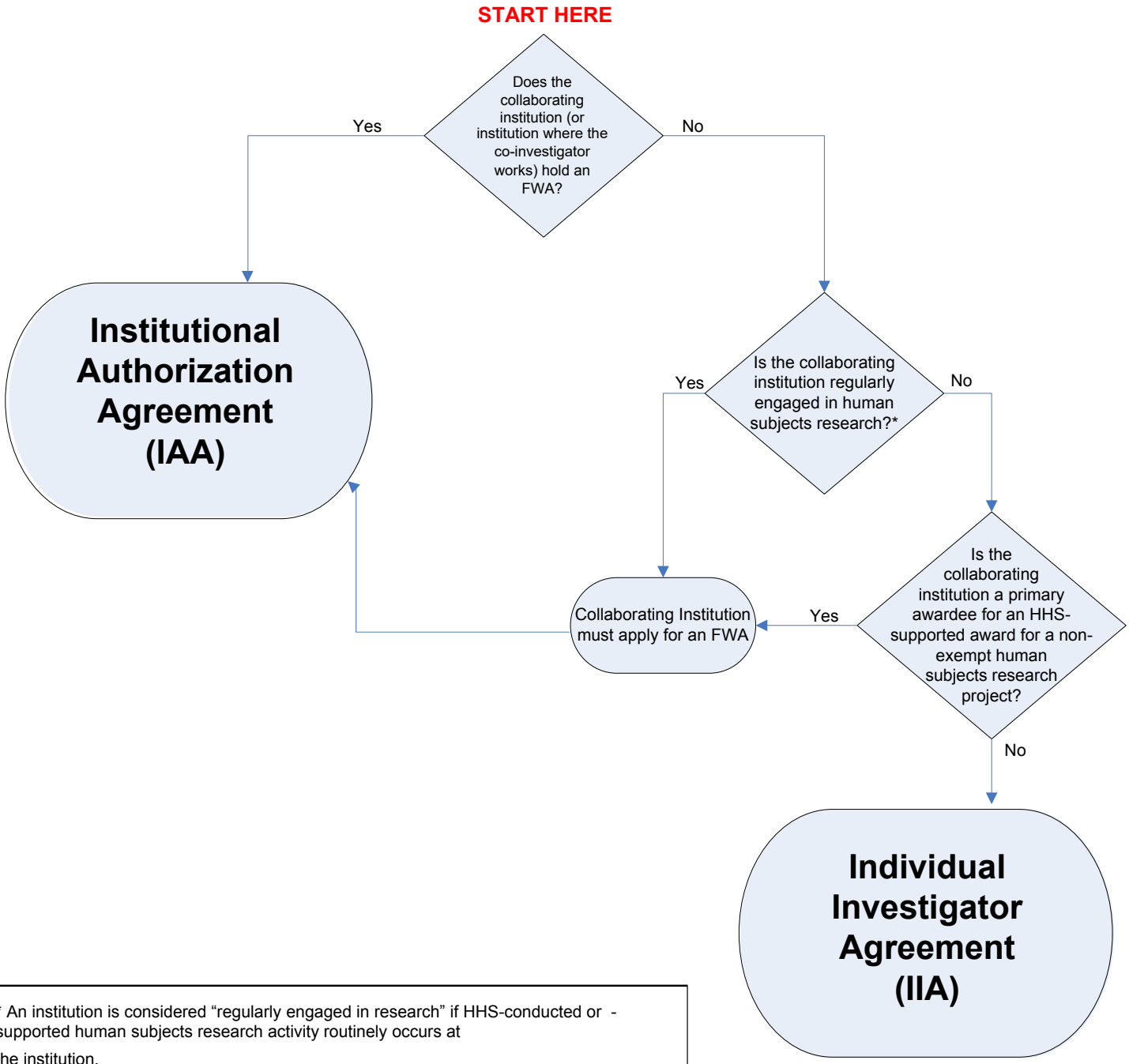
Do I Need An Institutional Authorization Agreement (IAA) or An Individual Investigator Agreement (IIA) For My Research?



* An institution is considered "regularly engaged in research" if HHS-conducted or -supported human subjects research activity routinely occurs at the institution.

** IRB review criteria include:

- The time and resources required to accept the review, given other demands;
- The expertise required for initial and continuing review;
- The ability to comply with requirements for "local" knowledge of the research context at the other institution;
- The resources, ability, willingness of the other institution to handle complaints, review adverse events, and to monitor compliance with applicable laws and regulations and IRB requirements, and
- Whether single IRB review is required by the sponsor
- The risk level of the study
- Whether the study is FDA-regulated and/or a clinical trial