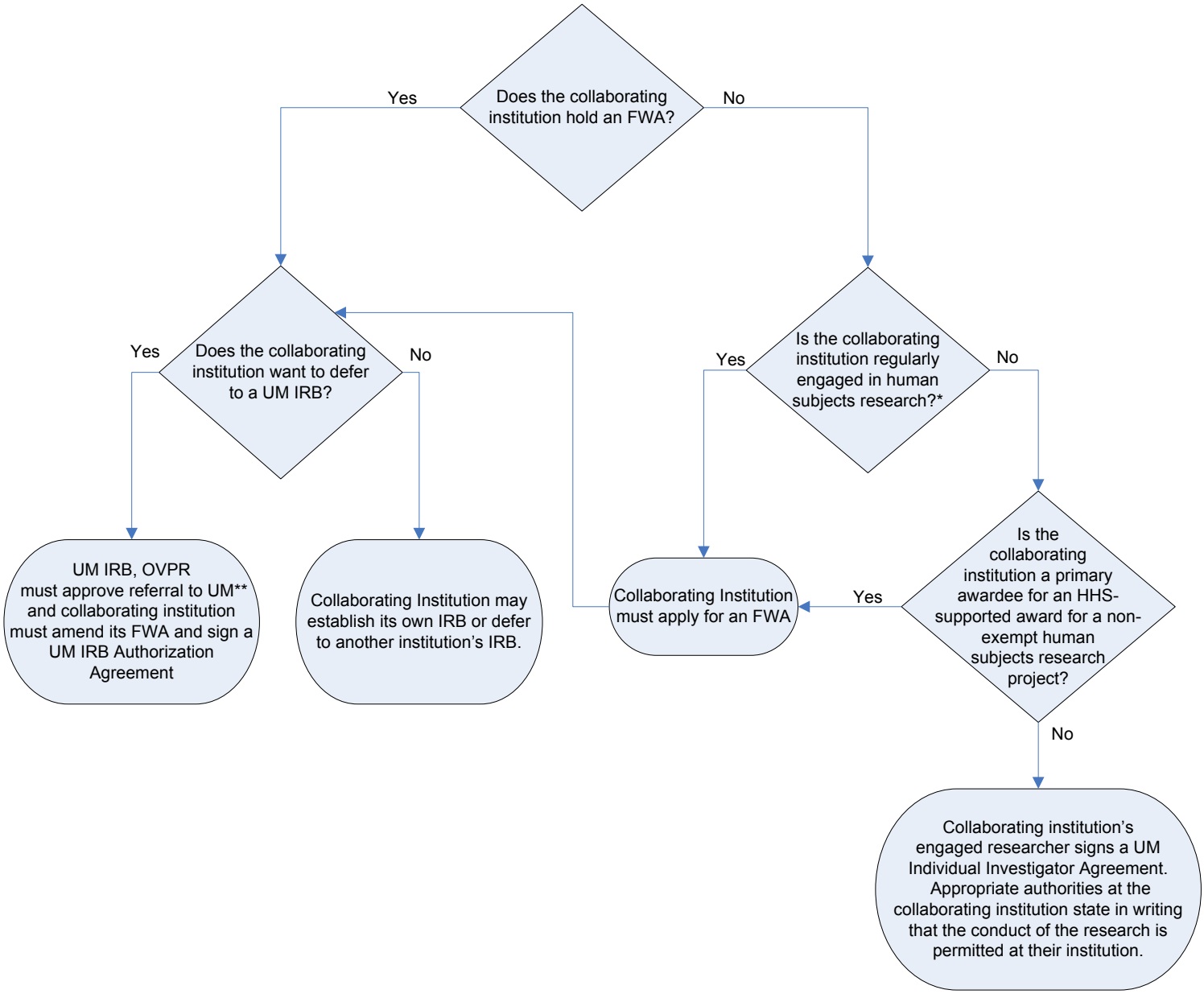
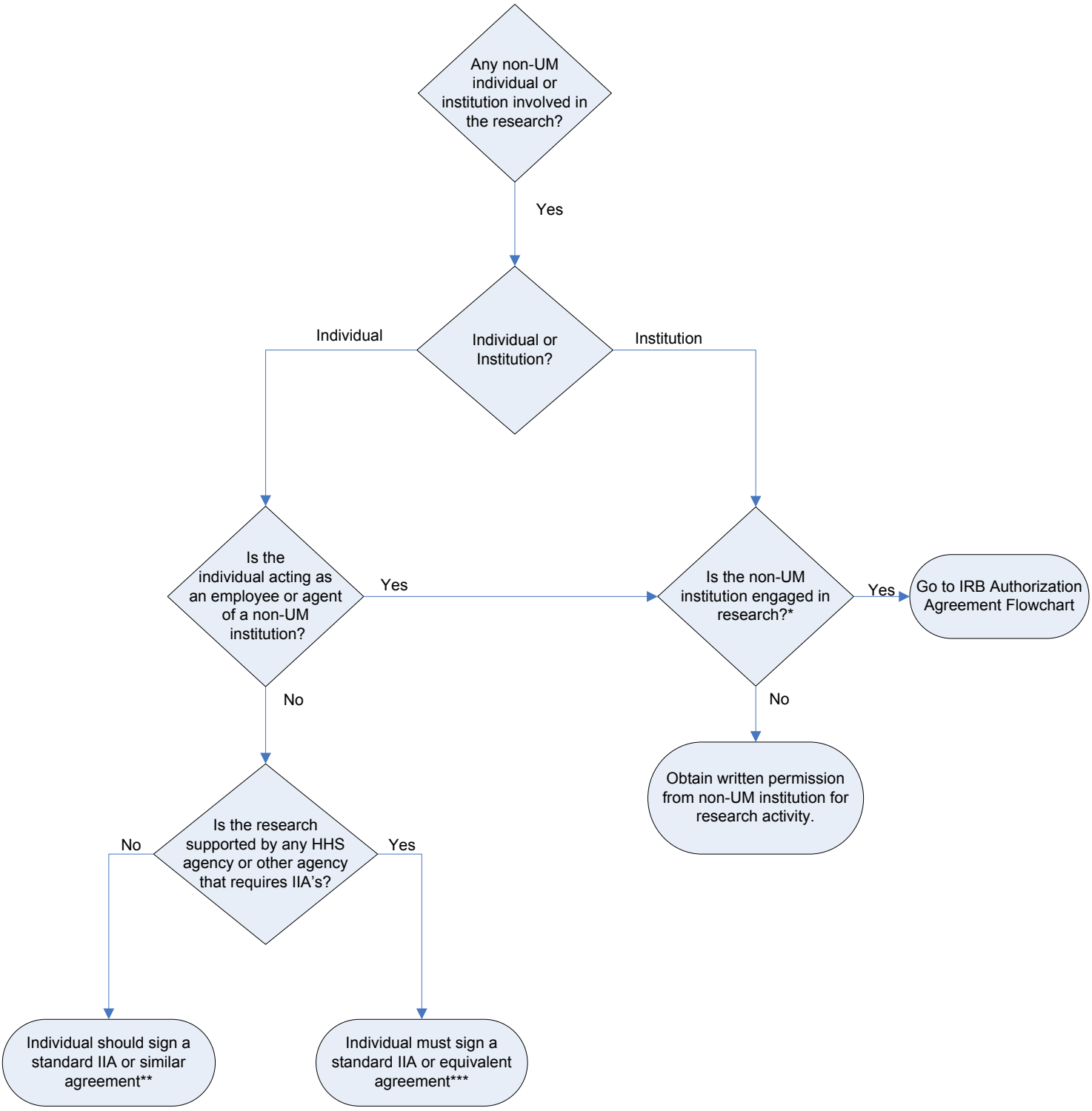
Federal Funding From DHHS or Another Federal Agency Requiring FWAs



* An institution is considered "regularly engaged in research" if HHS-conducted or -supported human subjects research activity routinely occurs at the institution. (See http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm)

** 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 outside organization and any research sites;
- The resources, ability, willingness of the outside organization, the principal investigator and the research sites to handle complaints, review adverse events, and to monitor compliance with applicable laws and regulations and IRB requirements, and
- The ability and willingness to comply with any additional requirements the outside organization my impose on the UM review.

Is an IRB Authorization Agreement or Individual Investigator Agreement 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 inhstitutionally delegated authority or responsibility. (See http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm)

** Consult with the IRB. Exceptions may be made based on literacy, nationality, or cultural consideration.

*** The IRB may grant an exception in cases involving literacy or technology constraints.