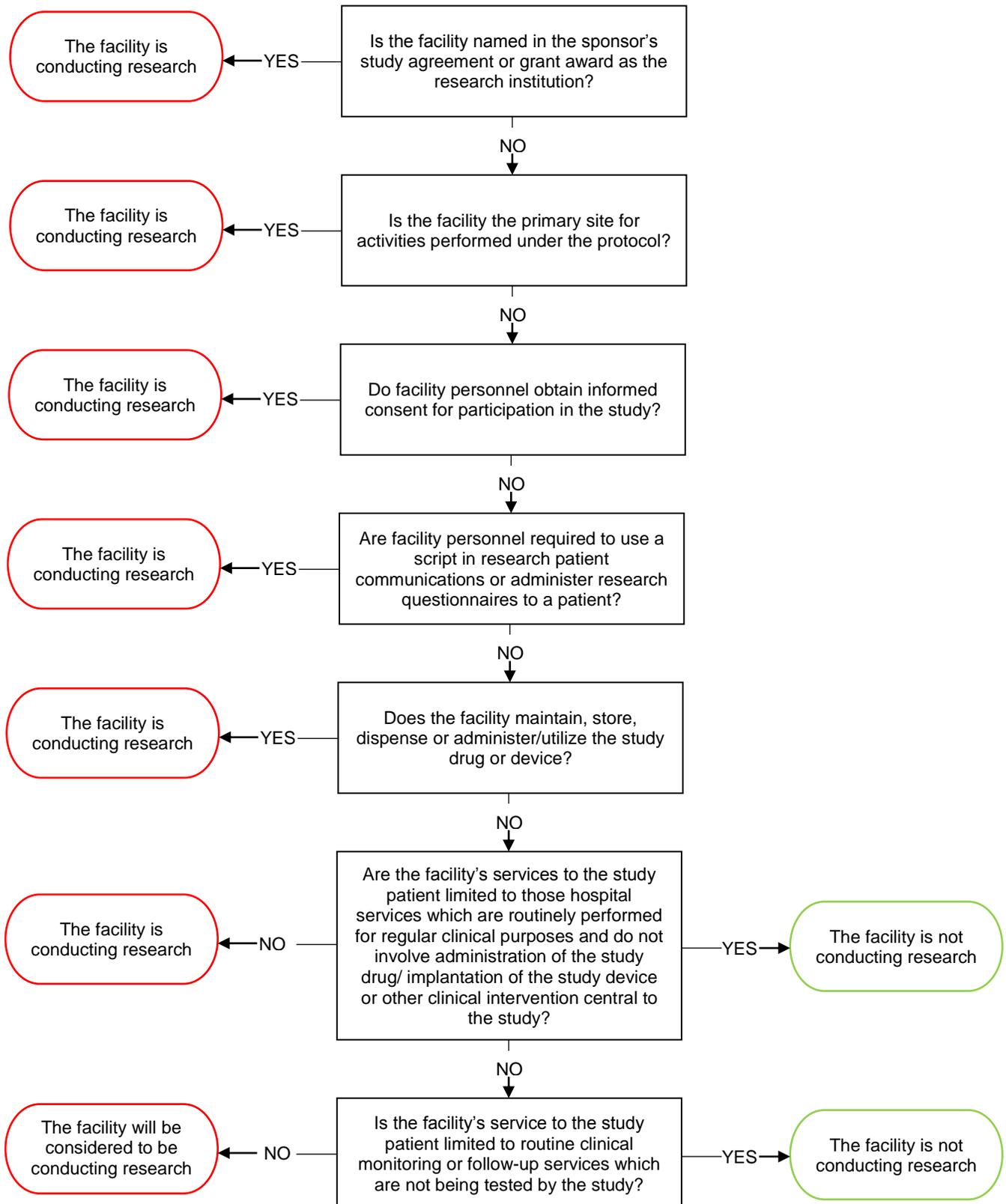


Process for Determining if Facility is Conducting Research



Research activities at Tenet facilities are subject to Tenet's research policies and program. Involvement in research which does not rise to the level of "conducting research" does not require approval by the Tenet facility's designated IRB and may meet the criteria to be carried out pursuant to the policy flash.

Examples of situations in which the facility is "conducting research"

- The hospital maintains a supply of the study drug in the hospital pharmacy.
- The study drug is administered at the hospital for most of the research patients. If the drug is only rarely administered in the hospital if a study patient requires hospitalization as a part of standard of care, this may not be considered research on the part of the hospital.
- A study device is used or implanted at the hospital.
- A radiology procedure involves use of an added coil for a study MRI
- The Principal Investigator is employed by Tenet and performs research visits in the Tenet practice offices as part of his employment duties
- The hospital allows another institution to perform research on its premises (example, a PI's research coordinator visits patients admitted to the hospital to complete a quality of life survey) vs. coming to enroll the patient

Examples of situations in which the facility is not "conducting research"

- Hospital personnel tell a patient that a research program is available and may direct the patient to the investigator or ask the patient's permission to provide her information to investigator.
- The hospital provides reference lab services for samples obtained by the investigator and delivered to or retrieved by the hospital lab
- The hospital obtains blood or tissue samples and provides them to the investigator or a central lab for analysis
- The hospital provides a routine radiology procedure, without use of any study drug as a part of or contemporaneous with the procedure and without modification to the radiology procedure dictated by the protocol (example, a prescribed number of CT views at required intervals different from the customary manner in which the CT would be performed)