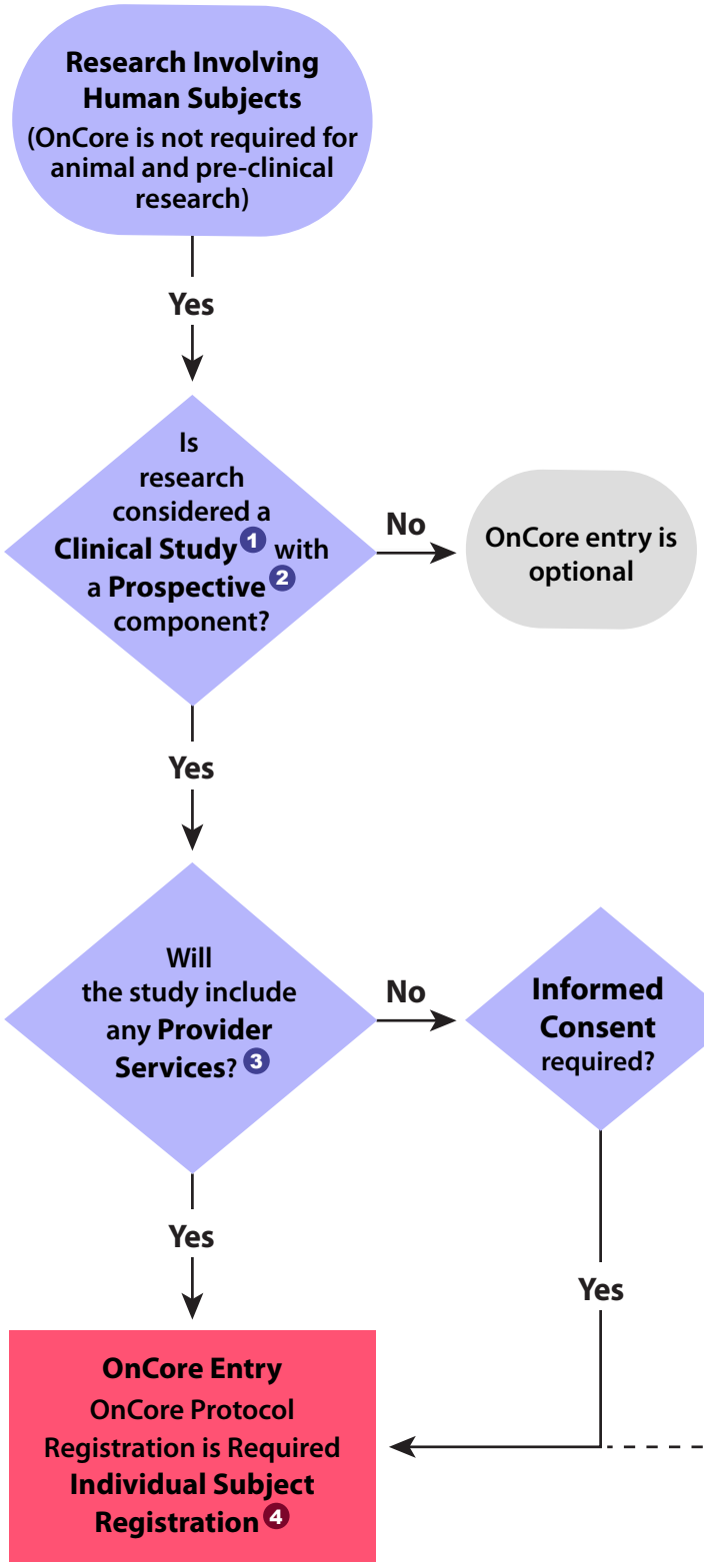
OnCore®CRMS Registration Requirements for Clinical Research at Indiana University and IU Health



1. **Clinical Study:** A research study using human subjects to evaluate biomedical or health-related outcomes. This includes, but is not limited to, prevention and treatment of a disease/diagnosis or genetic and environmental factors related to disease and health; studies surrounding cost of care or regarding patient satisfaction; observations surrounding a disease/diagnosis and patient health; specimen or tissues collections; and registries.

2. **Prospective:** Study data collection looks forward using either one-time or periodic observations collected predominantly following subject enrollment. This could occur during a single visit or thoroughtout a series of visits.

3. **Provider Services:** A broad term used here to describe the services (diagnostics, assessments, treatment, etc.) provided to patients by any healthcare professional (physician, nurse, technician or other) as part of the study. If these services are provided, this question should be answered as yes, rgardless of whether the services are paid for by the study or by a third-party payer.

4. **Individual Subject Registration** is required for studies that
   - require ***safety flags*** in the EMR (i.e., PowerTrials)
   - require ***monitor access*** to patient data in Cerner
   - require ***Medicare Coverage Analysis***
   - require ***Research Billing*** tools in OnCore
   - are categorized as ***Interventional***
   - require ***IU specimen storage*** services
   - use ***Advarra Participant Payments***