OFFICE OF CLINICAL RESEARCH FOR INDIANA

OnCore Registration Requirements

All studies that involve patients, biological samples of patients, or access to medical records of patients with cancer or at immediate risk for cancer or cancer survivors must be entered into OnCore. These studies may not meet the institutional requirements in the diagram below, but entry for review by the Cancer Center Scientific Review Committee (SRC) is mandatory. For additional questions regarding SRC requirements for cancer studies, please contact *crosrc@iupui.edu.*

DEFINITIONS

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.

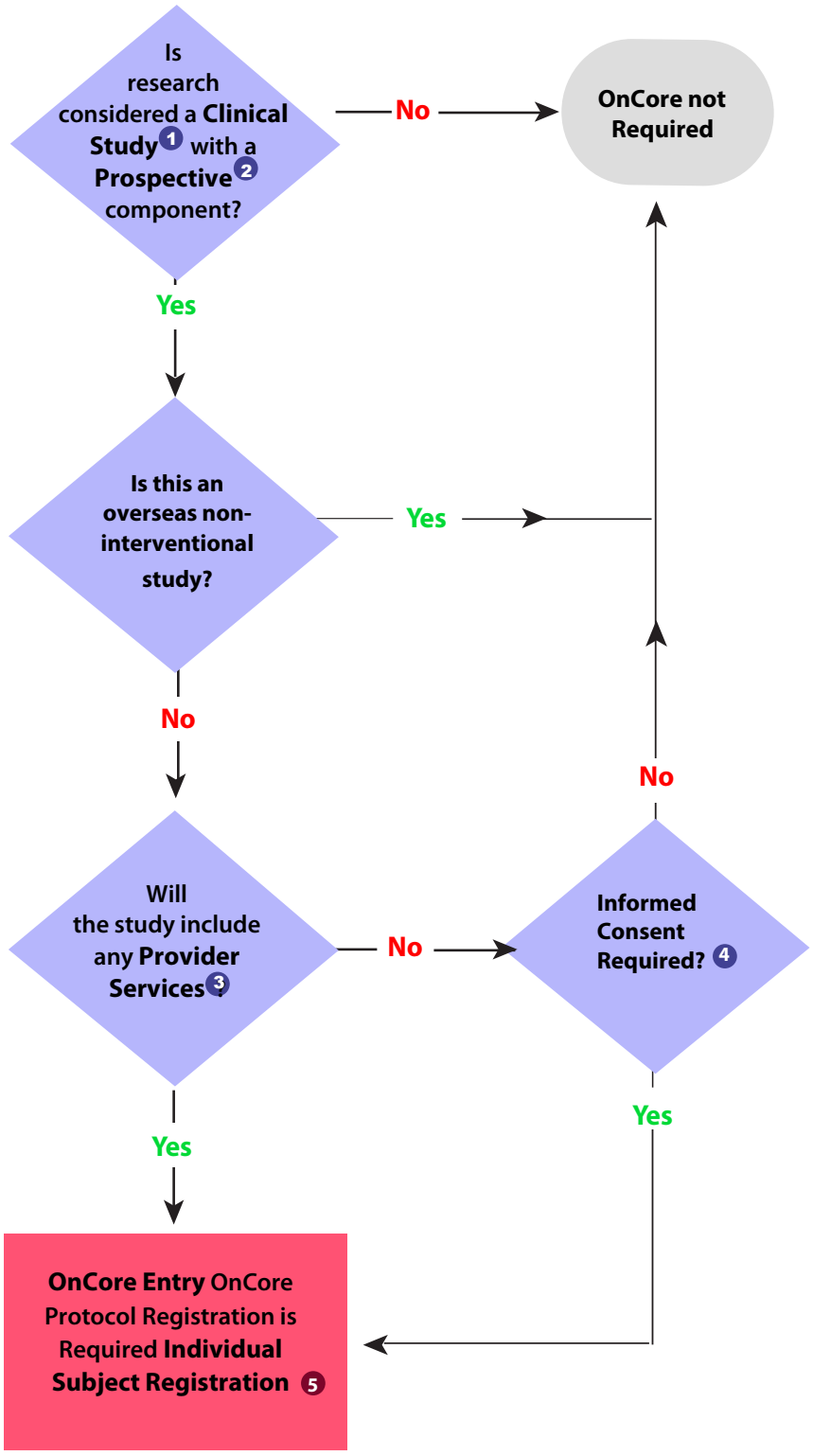
2. **Prospective:** Study data collection looks forward using either one-time or periodic observations collected predominantly following subject enrollment. This could occur during a single visit or thoroughtout a series of visits.

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, regardless of whether the services are paid for by the study or by a third-party payer.

4. **Informed Consent:** A process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical study. Consent may be documented and with signature, verbal, or assumed.

5. **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***

   For studies that do not meet the individual registration requirements listed, an application for Summary Accrual may be submitted. Please contact oncore@iu.edu for more information



Office of Clinical Research of Indiana
(317) 278-2600 | OnCore@iupui.edu