OFFICE OF CLINICAL RESEARCH FOR INDIANA

OnCore Registration Requirements

Certain research studies that fall outside the institutional requirements illustrated in the diagram may still qualify for entry into OnCore:

1. ***Any studies where objectives involve the diagnosis, prevention, screening, evaluation, treatment or support of patients at immediate risk of cancer, cancer patients, or cancer survivors or any studies where at least 25% of the patients involved in the study are likely to have an active cancer diagnosis. These studies require review by the Cancer Center Scientific Review Committee (SRC). For additional questions regarding SRC requirements for cancer studies, please contact crosrc@iu.edu.***

2. ***Any studies with procedures that are billed through IU Health. IU Health Research policy requires the Office of Clinical Research to complete a billing compliance review for studies with procedures that may potentially be billed through their system. For additional questions regarding research billing compliance, please contact ocrfin@iu.edu.***

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 thoroughout a series of visits.

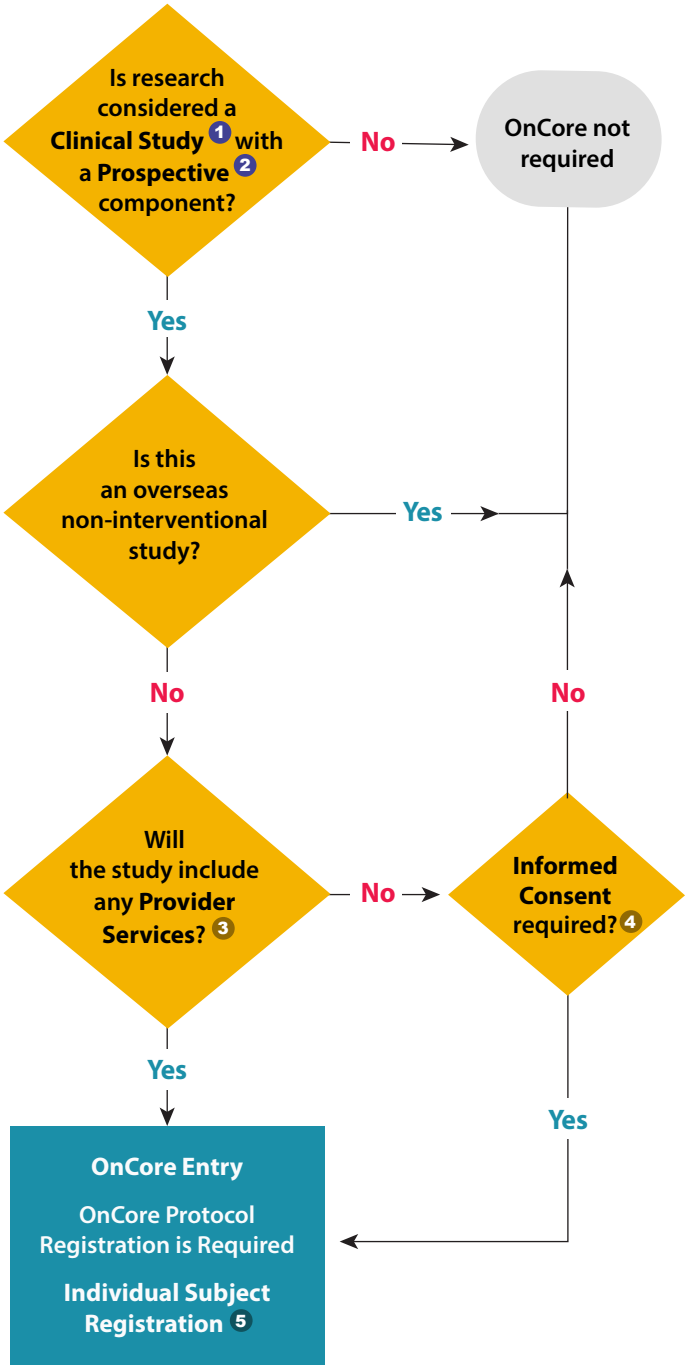
3. **Provider Services:** A broad term used here to describe the services (diagnostics, assessments, treatment, etc.) provided to patients by any healthcare professional (physician, nurse, technician or other) as part of the study. If these services are provided, this question should be answered as yes, 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 with signature, verbal, or assumed consent.

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 Health patients to provide written informed consent

*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 for Indiana | 317-278-2600 | oncore@iu.edu