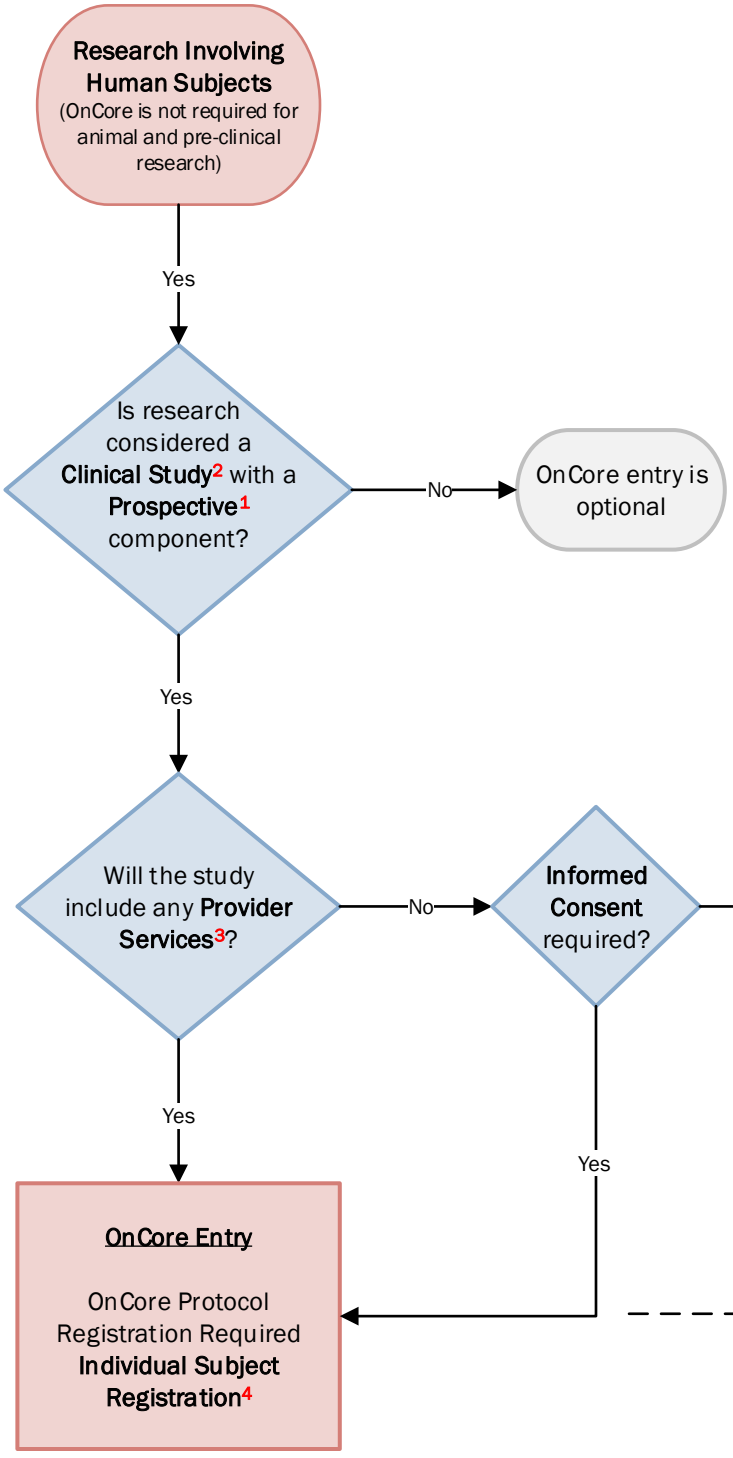
OnCore® CRMS Registration Requirements

For Clinical Research at Indiana University and IU Health



[1]**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 throughout a series of visits.

[2]**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; prevention and treatment of genetic and environmental factors related to disease and health; studies surrounding cost of care; studies regarding patient satisfaction; observations surrounding a disease/diagnosis and patient health; specimen or tissues collection; and registries.

[3]**Provider Services**: Provider services is a broad term used here to describe the services (diagnostics, assessments, treatment, etc.) of any healthcare professional (physician, nurse, technician and others) to patients as part of the study. 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]**Individual Subject Registration** is required for the following:

- Studies requiring ***safety flags*** in the EMR (i.e. PowerTrials).
- Studies requiring ***monitor access*** to patient data Cerner.
- Studies requiring ***Medicare Coverage Analysis***
- Studies requring ***Research Billing*** tools in OnCore
- Studies categorized as ***Interventional***
- Studies requiring ***IU specimen storage service***s.
- Studies utilizing **Forte Participant Payments**

Summary Accrual option:

An application for ***Summary Accrual*** may be submitted for any studies that do not meet the ***Individual Subject Registration***[4] requirements listed above.

INDIANA UNIVERSITY

Indiana University Health