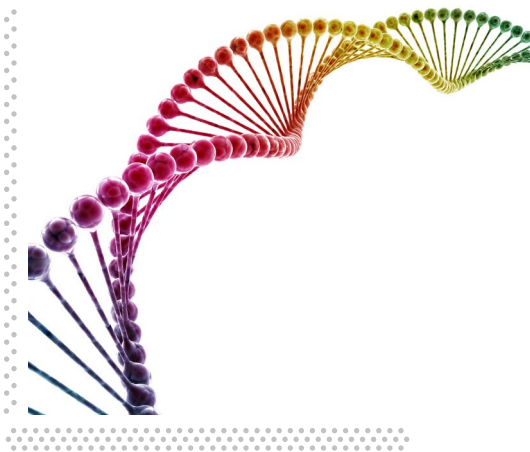

School of Medicine

Clinical Research

OFFICE OF CLINICAL RESEARCH

August 2025

- 1. Indiana Biobank Update*
 - 2. Clinical Study Dashboard Update*
 - 3. Do You Know Your OnCore Status?*
-



Indiana Biobank Update

In support of the IU School of Medicine and IU Health's joint enterprise goals, the Indiana Biobank continues to expand its efforts to collect DNA samples from patients across the state.

Patients are invited to provide samples to the Indiana Biobank through Twistle's text messaging platform. Additionally, in collaboration with IU Health, the Indiana Biobank team is developing both a patient consent mechanism during self-registration at the time of their visit and a self-guided enrollment process empowering patients to participate in research at their own convenience.

Thanks to these enhanced enrollment strategies, DNA sample collections have significantly increased. Genetic data generated from these samples—paired with de-identified electronic medical record (EMR) data—is now available to approved researchers across a range of studies.

Looking ahead, a new self-service portal is launching this fall. This platform will allow researchers to browse available clinical and genetic datasets, and conduct analyses directly within the secure portal environment. overall process.

For both investigators and the OCR, the project aims to simplify the study activation process.



Clinical Study Dashboard Update

In consultation with multiple experts on the subject, leadership, and external benchmarks, the OCR has developed a dashboard that will track the Clinical Study Portfolio's overall progress, the performance of individual support groups and workflows, and the execution of individual studies. Additionally, these metrics will provide valuable insight into the overall study process, helping to streamline and optimize for future studies.

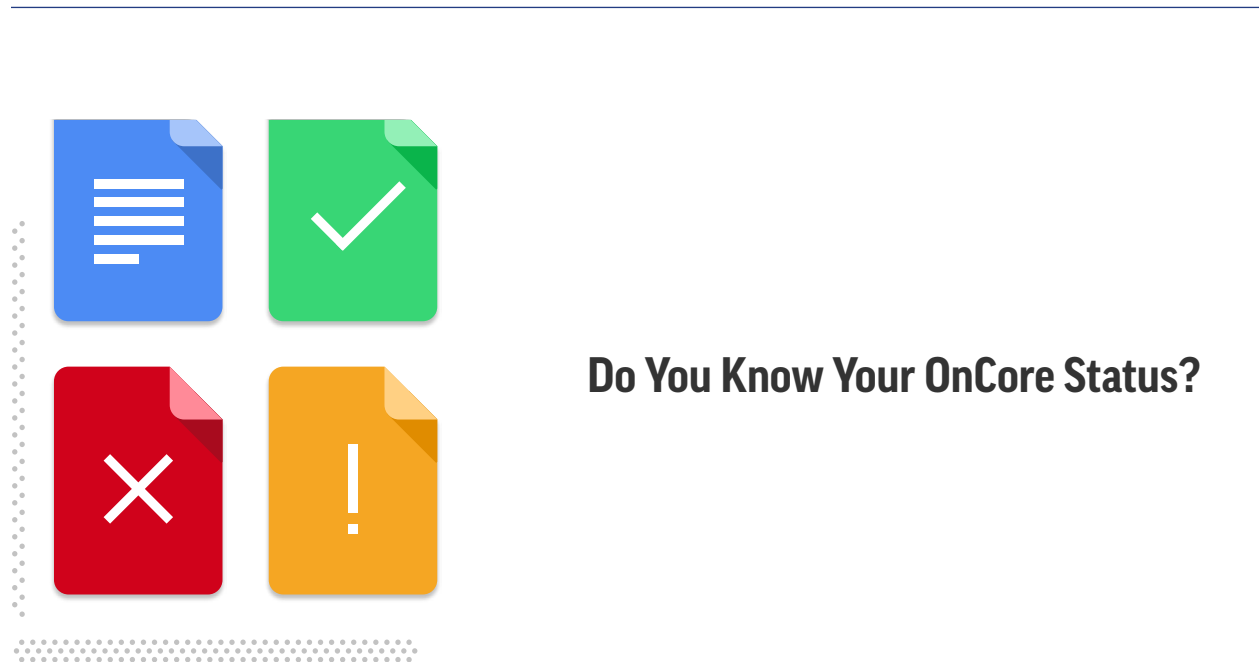
The dashboard's **Clinical Study Portfolio Enterprise Metrics** will track the entirety of the portfolio. These metrics will track the progress made toward the 10-year enterprise clinical research goal and biobank enrollment.

The **Aggregate Study Activation Metrics** will track the progress of study preparation workflows, such as turnaround times for the Institutional Review Board (IRB), OCR/Office of Research Administration (ORA) contracting, and coverage analysis.

The **Clinical Study Execution Key Performance Indicators (KPIs)**, a group of broadly-accepted metrics, will track the execution of individual studies within the portfolio. Both academic and industry institutions use such KPIs to track the progress of clinical studies. These metrics include tracking study activation timeframes, Investigational Drug Services drug delivery performance, and timing around the first enrolled patient.

The **Clinical Study Portfolio KPIs** evaluate the number of studies open to accrual and the rate of trial enrollment across the portfolio.

The full definitions of individual metrics within these groups are available in *PDF form*. If you'd like to provide feedback on these metrics, please do so at the link below.



This summer, the OCR and Indiana Clinical and Translational Sciences Institute (CTSI) are embarking on a major effort to refresh and streamline our clinical research data.

Accurate and up-to-date information in both OnCore and the All IN for Health TrialX Connect System strengthens our research, keeps us competitive, and ensures Indiana's diverse communities are well represented. If you've heard from Brenda Hudson or Alina Adkins recently, it's all part of this important push for excellence.

Additionally, we're developing standard procedures to help everyone maintain accurate study records, with more guidance coming in a future newsletter and CRES sessions. Thank you for assisting with this process!

Do you think your study status is accurate in OnCore? Not sure? Feel free to check. A good way to tell is if your study is no longer recruiting, the status should be “Closed to Accrual.” If your study is closed at the IRB, enter all remaining study information (including participant data) in OnCore and then change the OnCore status to “IRB Study Closure.”

Do you need a refresher on what the OnCore status codes are and what they mean? If so, here’s a diagram explaining them all.

OnCore Protocol Status	What the status means
New	<ul style="list-style-type: none"> Automatically assigned when a protocol is first entered in OnCore. The date can be edited.
SRC Approval (Cancer Center Only)	<ul style="list-style-type: none"> Cancer Center Studies Only Date of Scientific Review Committee Approval, populated from ePRMS once approved by the SRC.
IRB Initial Approval	<ul style="list-style-type: none"> Indicates the date the IRB approved the protocol, status automatically populates when the IRB Approval is entered in the PC Console > Reviews tab.
OCR Signoff	<ul style="list-style-type: none"> Shows coverage analysis is finalized by the OCR and the final contract and informed consent are reviewed for consistency.
Account Signoff (Cancer Center Only)	<ul style="list-style-type: none"> Completed by the IUSCC once the budget is reviewed and approved.
Research Unit Signoff	<ul style="list-style-type: none"> Designates that all required reviews are done, sponsor authorization obtained, and the study team is ready to begin seeing patients. OnCore calendar and budget should also be reviewed.
On Hold	<ul style="list-style-type: none"> Study not yet opened to accrual, and work is stopped until an issue is resolved. Can be used before “Open to Accrual” but not after.
Abandoned	<ul style="list-style-type: none"> Indicates study was withdrawn before IRB approval, no further action expected.
Open to Accrual	<ul style="list-style-type: none"> Shows research team has study open locally to accrual/enrollment. All required reviews are complete, sponsor authorization obtained, and the research group is ready to begin seeing patients.
Suspended	<ul style="list-style-type: none"> Shows temporary suspension of the protocol and subject accrual. It is only used after a study is opened to accrual.
Closed to Accrual	<ul style="list-style-type: none"> Indicates when the protocol is no longer enrolling subjects. Other study procedures or follow-up can still be occurring. Indicates protocol is still open in IRB.
IRB Study Closure	<ul style="list-style-type: none"> Indicates the protocol ran its intended course and was closed with the IRB or expired and will not be reapproved.
Terminated	<ul style="list-style-type: none"> Indicates the protocol ended prior to completing the expected outcome and has been terminated with the IRB. It may also be used after the IRB study closure to indicate that no further action is required on the study (i.e., financials reconciled).

Questions? Reach out to the [OnCore Team](#). More details on updating your study status are available on the OCR website under “[OnCore Support Documents-Protocol Minimum Footprint](#).”

IU School of Medicine
340 W 10th St
Indianapolis, IN 46202

[View online](#)