ONCORE PROTOCOL CREATION AND SET-UP

Protocols are the foundation of all OnCore functionality and features. Basic protocol information, sometimes referred to as a "minimum footprint", should be entered into OnCore before building calendars, creating a protocol budget, enrolling subjects, tracking subject visits, invoicing sponsors, or running reports.

WHAT UF STUDIES NEED ONCORE ENTRY?

- UF Cancer-related studies reviewed by the Scientific Review and Monitoring Committee.
- Any other UF Human Subjects Research studies that include at least one of the following:
  - Prospective assignment of subjects
  - Intervention with therapeutic intent
  - Measurement of health or behavioral outcomes
  - Collection of health-related biomedical or behavioral data or samples
  - Data collected in a clinic, hospital, research space, or the UF Clinical Research Center
  - Sponsor invoicing
  - Billable patient care costs

When new studies are submitted to the OCR, they are entered into OnCore. As older "legacy" studies are submitted to OCR for an amendment or revision, they are also added. In addition, departments may choose to have other studies entered into OnCore to simplify the management of their research portfolio.

ONCORE PROTOCOL LEVELS

Several factors determine how much of the OnCore functionality is set up and used on a given study. For example, some legacy studies may only take advantage of the OnCore record or "shell", while a newer study might also use the calendar, budget, and/or invoicing modules, depending on the nature of the study. During its review, the Office of Clinical Research (OCR) determines the scope/level of a given study/project, which in turn, determines which OnCore fields and modules are required.

OnCore Implementation: Scope of project builds

OnCore Record or "Shell"	Record & Calendar	Record & Budget	Record, Calendar & Budget
Protocol tracking	Protocol tracking	Protocol tracking	Protocol tracking
IRB tracking	IRB tracking	IRB tracking	IRB tracking
Deviations tracking	Deviations tracking	Deviations tracking	Deviations tracking
Portfolio management	Portfolio management	Portfolio management	Portfolio management
Participant management • Patient statuses • Consent dates	Participant management • Patient statuses • Consent dates	Participant management • Patient statuses • Consent dates	Participant management • Patient statuses • Consent dates
	Visit tracking • Calendar management • Upcoming visits • Missed and rescheduled visits		Visit tracking • Calendar management • Upcoming visits Missed and rescheduled visits
		Sponsor invoicing	Sponsor invoicing
		Accounts receivables management	Accounts receivables management

ONCORE LIBRARIES

When a protocol is created in OnCore, it is assigned to a library. The library determines which fields, drop-down lists, and signoffs are available for the protocol to use.

UF OnCore has two libraries:

- **Oncology Library** – For "cancer relevant" studies that
  - Enroll patients with a known or suspected diagnosis of cancer as part of the eligibility criteria; or
  - Include research endpoints related to cancer, associated symptoms, or established cancer risk factors (including smoking and tobacco-associated studies, surveys, hepatitis or HPV vaccines, etc.); or
  - The local PI plans to exclusively enroll current, former or potential cancer patients into the study
- **Academic Health Center Library** – For Non-oncology studies

WHO CREATES THE PROTOCOLS IN ONCORE?

- **Oncology Studies**
  - All "cancer relevant" studies that are conducted on the UF Health Gainesville campus or UF Health Proton Therapy Institute must be reviewed by the UF Health Cancer Center's Scientific Review and Monitoring Committee (SRMC), which is also known inside of OnCore as the **Protocol Review and Monitoring Committee (PRMC)**.
  - Most "cancer relevant" study shells are set-up/created either by the SRMC administrative staff or Cancer Center staff prior to SRMC review.
  - If a "cancer relevant" study is submitted to the Office of Clinical Research (OCR) **BEFORE** the shell has been created for the SMRC review, **OCR staff** will create the shell and inform the SRMC administrative staff so that a duplicate shell is not created.
  - If a protocol shell has been set-up by SRMC or Cancer Center and it is later determined through the OCR review that additional fields or modules are needed (e.g. budgets, calendars, billing grids), **OCR staff** will add the additional required fields.
- **Academic Health Center Studies**
  - All non-oncology Academic Health Center shells are set-up/created by Office of Clinical Research (OCR) staff.

WHAT FIELDS ARE SET UP BY OCR DURING PROTOCOL CREATION?

	Data Field	Tab	Definition
01	Protocol No.	Main-Details	Auto-generated OnCore number
02	NCT Number	Main-Details	As available, from Clinicaltrials.gov
03	Library	Main-Details	Academic Health Center/Oncology
04	Department	Main-Details	Home department of PI per UF Health directory
05	Organizational Unit	Main-Details	Academic Health Center/Cancer Center
06	Title	Main-Details	Full study title (should match title that will be submitted to IRB)
07	Short Title	Main-Details	As available, from the Clinicaltrials.gov Brief Title
08	Study Phase	Main-Details	If available/applicable
09	Age	Main-Details	**ADULTS**: 18 years and older **CHILDREN**: under 18 years **BOTH**: under and over 18 years
10	Investigator Initiated Protocol	Main-Details	**YES**: The PI is the principal sponsor **NO**: The PI did not write or collaborate on protocol
11	Summary Accrual Info. Only	Main-Details	**YES**: Observational studies with no clinical services **NO**: Interventional studies or observational with clinical services
12	Protocol Type	Main-Details	**INTERVENTIONAL**: Manipulation of the subject or environment to change health-related biomedical or behavioral processes or outcomes **OBSERVATIONAL**: No manipulation of the subject or environment intended to change outcomes/processes *Oncology studies will list NCI protocol type
13	Investigational Drug	Main-Details	**YES**: At least one IND-regulated drug **NO**: No IND-regulated drugs
14	Investigational Device	Main-Details	**YES**: At least one IDE-regulated device **NO**: No IDE-regulated devices
15	RC Total Accrual Goal (lower)	Main-Details	Target Enrollment - Number of subjects needed to (1) fulfill contractual obligations or (2) run the proposed analysis to answer the research
16	Accrual Duration (Months)	Main-Details	Estimated number of months enrolling new participants

	Data Field	Tab	Definition
17	IRB Number	Main-Management	IRB number (if known at time of set-up)
18	Management Group	Main-Management	OnCore Management Group(s)
19	Principal Investigator	Main-Staff	Principal Investigator's name (Should match IRB PI)
20	Primary Study Coordinator	Main-Staff	Coordinator name(s)
	Study Staff (other)	Main-Staff	Any other staff known at time of set-up
21	Principal Sponsor	Main-Sponsor	"Owner" or author of study protocol, **Principal Sponsor** checkbox marked **Y**
	Sponsor (other)	Main-Sponsor	Any other sponsors known at time of set-up
22	Sponsor Protocol No.	Main-Sponsor	As available, the Sponsor Protocol Number and the Study's Nickname or acronym, separated by a semicolon.
23	Institution	Institution	University of Florida

ADDITIONAL FIELDS

Once the basic fields are set-up, the OnCore protocol can be reviewed by SRMC, the OCR, and the study team (as applicable). Other OnCore data fields will then be completed by OCR or SRMC as needed for additional OnCore functionality or workflows.