

## OnCore Intake Submission Form – User Instructions

This form is for OnCore users in departments who have been fully deployed in OnCore. All new users that have not been trained in OnCore must complete a Service Now ticket for training prior to completing this form.

Note that if this form is not marked Complete at the end of submitted entries, the Clinical Trial Management System Operations Office (CTMS Ops) Team will not receive the request.

REDCap Question	Definition	Comments
Project ID	Identifier assigned by REDCap	
Today's Date	Date request is added to REDCap	
Submitter First Name	Name of person adding to REDCap	
Submitter Last Name	Name of person adding to REDCap	
Submitter Email Address	Enter email of contact person.	
Does your study meet the criteria for Policy 2317?	If yes, study must be entered into OnCore so it can be pushed into EPIC per Policy 2317. If no, study can remain in OnCore and pushed into EPIC upon request.	Use additional comments section to detail further instructions for the CTMS Ops Team.
What services are you requesting?	Choose service(s) you are requesting CTMS Ops Team to complete.  Protocol Shell = All items within the minimum footprint report.  Calendar and budget build = All items built in the study calendar and financials.  Coverage Analysis Only = Coverage Analysis is developed by CTMS Ops Team. Study team has built calendar, budget, and protocol shell.	Once you choose your service, the form will take you to the section relevant to your request.
Does this study have any deadlines or due dates the CTMS Ops team should be aware of when creating the study in OnCore? Describe Study Deadline/Due Date.	Indicate specific deadlines or due dates related to urgency of completion by the CTMS Ops Team.	

REDCap Question	Definition	Comments
Estimated Date of Study Opening in Oncore	Date study is requested to be “open to accrual” in OnCore. Requests should allow time for CTMS Ops Team to complete entire build.	
Do the accruals count towards the Cancer Center grant?	Question relates to Cancer Center studies only.	Your answer will lead you to the OnCore service path relevant to your request.
Primary Management Group - Oncology	Indicate specific Oncology group that is primary to managing study. Typically relates to PI’s home department.	Your answer will lead you to the OnCore service path relevant to your request.
Does this study require Scientific Peer Review (SRC or PRMS)?	Question relates to Cancer Center studies only.	Your answer will lead you to the OnCore service path relevant to your request.
Your study will now be routed for coverage analysis and QA check. Please upload the protocol, budget, and internal budget. We will reach out to you if we have any questions.	Question relates to Coverage Analysis only request. All pertinent documents must be uploaded so CTMS Ops Team can complete request.	
Protocol Number	Must include UC Davis IRB number for studies in OnCore. You may use IRB number assigned to study even if submission is not complete.	
NCT Number	Indicate National Clinical Trials.gov number when applicable (Calendar/Budget builds). If not available, list explanation in comments section.	
Administering Department	Indicate specific group that is primary to administering study. Typically relates to PI’s home department.	
Study Site	Indicate site where study will primarily be managed.	
Project Title/Name	Provide the full project or study title.	

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Study Short Title	List the study short name or acronym that you will be using to refer to study. Short title is typically used to search study title in EPIC.	
Phase	Indicates Phase number typically referred to in study protocol. If no phase, choose "0".	
Protocol Type	Indicates the type of protocol for reporting purposes. <a href="#">Definitions of protocol type</a>	
Other	Describe "other" protocol type other than what is listed.	
Investigator Initiated	Indicate if investigator initiated	
Study Population	Indicate type of population	
Is this an investigational drug or device study?	Indicate whether investigational drug or device study.	Your answer will lead you to the OnCore service path relevant to your request.
Comparative treatment?	Indicate type of treatment other than IND/IDE (e.g., therapy comparisons)	Your answer will lead you to the OnCore service path relevant to your request.
Investigational Drug	Indicate yes, no, or N/A. If investigational drug, list IND number or "exempt".	Your answer will lead you to the OnCore service path relevant to your request.
List IND ID #, Holder's Name	List Sponsor Name	
List Investigational Device Exemption (IDE) #, Holder's Name	List Sponsor Name	
List Investigational Device Exemption (IDE)#, Holder's Name	List Sponsor Name	
Is this a Multi-Site Trial?	Indicate yes or no depending on whether study is being conducted at multiple sites (e.g., institutions)	
Protocol Target Accrual All Sites	Indicate Study wide Overall Enrollment Number	

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REDCap Question	Definition	Comments
UCD Site Accrual Number	Indicate UC Davis Total Enrollment Goal	
UCD Site Accrual Duration	Indicate Duration to Enroll in Number of Months	
Anticipated Primary Completion Date	Indicate Study Wide Date that last subject will have last intervention	
Anticipated Completion Date	Indicate final date data will be collected for the last subject on the last visit	
UCD Site Accrual Number	Indicate UC Davis Total Enrollment Goal	
UCD Site Accrual Duration	Indicate Duration to Enroll in Number of Months	
Anticipated Primary Completion Date	Indicate Study Wide Date that the last subject will have last intervention	
Anticipated Completion Date	Indicate Final date data will be collected for the last subject on the last visit	
Primary Management Group - Medicine	Indicate specific Medicine group that is primary to managing study. Typically relates to PI's home department.	
PI First Name	Indicate Principal Investigator (first name and middle initial)	
PI Last Name	Indicate PI Last Name	
CRC Name	Indicate Name and Role	
Regulatory Coordinator Name	Indicate Name and Role	
Finance Contact Name	Indicate Name and Role	
Additional Study Staff	Indicate Name and Role	
Department Contact for Calendar Review	Indicate Name and Email	

REDCap Question	Definition	Comments
Department Contact for Coverage Analysis Review	Indicate Name and Email	
Sponsor Name and Protocol Number	Indicate Name and Number	
Sponsor Role	Indicate type of sponsor	
Funding Number	Indicate Fund account number for the sponsor when applicable.	
Grant Number	Indicate the sponsor award/grant number.	
Calendar Information	The OnCore Support Team will build the calendar for this protocol but will not enter financial information until a fully executed contract and budget are received. In order to build this protocol in OnCore, the visit structure and procedures must be clearly defined in the protocol. If this is unclear, it will cause delays in the build process. A Schedule of Events in table format can be helpful. You may use the Schedule of Events template below and modify as needed.	
Are you participating in all arms of the study?	Please describe (arms, cohorts, phases, etc.)	
What is the overhead amount?	Indicate the contracted overhead (indirect cost).	
Is the drug/device paid by the sponsors?	Indicate whether or not the sponsor is providing the drug or device for free.	
Does the study require items or services that are potentially billable to a subject or third-party payor?	Subject or third-party payor can include a Patient or Patient's insurance	
Do you want vendor payables set?	Vendor Payables = Costs incurred to the study such as IDS Fees, Radiology Fees, Stipends, etc..	

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What is the salary amount for CRC (hourly)?	Indicate the salary amounts to calculate internal budget costs for CRC. Include benefits	
What is the salary amount for PI (hourly)?	Indicate the salary amounts to calculate internal budget costs for PI. Include benefits	
Will you be utilizing the specification build in OnCore for sponsor invoicing?	Indicate if specification build is needed for sponsor invoicing.	
Location of study visits and procedures	List all locations where research services are being provided to calculate internal budget costs.	
Is the study inpatient or outpatient?	Indicate where services are being provided for study.	
Are there labs?	Indicate if UC Davis lab services are being utilized.	
Are the labs local or central?	Indicate where UC Davis labs are being performed to calculate internal budget costs. Provide CROC Form.	
How will labs be drawn?	Indicate how labs draws are being provided to calculate internal budget costs.	
Do the labs involve PKs?	Indicate if PK draws are being provided to calculate internal budget costs.	
Where do PKs take place? How many time points?	Describe where PKs are provided to calculate internal budget costs.	
Are Radiology Services being utilized?	Indicate if UC Davis Radiology Services are being provided to calculate internal budget costs.	
Where are Radiology services provided?	Indicate where Radiology Services are being provided to calculate internal budget costs. (e.g., Radiology/IRC)	

REDCap Question	Definition	Comments
What CCRC resources will be utilized?	Indicate if CCRC Services are being provided to calculate internal budget costs. (labs, CCRC nurse, staff, clinic space, etc.)	
What Cancer Center resources will be utilized?	Please describe labs, clinic space, staff, etc.	
Additional Comments	Add other clarifying comments needed for CTMS Ops Team to build your study in OnCore	
Upload additional documents as indicated in REDCap Intake Form		