

## ePRMS Initial Submission SOP

### Purpose

This SOP describes the procedure to enter and submit a protocol to the Protocol Review Committee (PRC) via the ePRMS Submission Console in OnCore for Initial review of cancer related protocols.

### Scope

The initial review process begins with the Submitter entering the protocol data into the ePRMS Submission Console and ends with the protocol staff being notified of the PRC's decision.

### Responsibility

Protocol Coordinators are responsible for entering and submitting a new protocol into the ePRMS Submission Console for initial review.

### Procedures

#### Send a Submission for Review

1. Choose the ePRMS, Submissions Console from the OnCore menu across the top of the screen.
2. On the left hand menu, under Create Submission, choose Initial Review (first option).
3. The review type defaults to FULL, which applies to all protocols.
4. Enter the protocol information into the Submission Electronic Form as follows. All fields listed below should be completed unless specified otherwise in the description.

Protocol Details	
Field:	Details:
Library	Oncology
Review Type	Full (Default)
Protocol Number	Sponsor protocol number or short title is suggested for submission. The protocol will receive a PRC assigned number upon being placed on agenda. The PRC assigned number should be replaced with the IRB number once received.
NCT Number	The protocol identifier assigned by clinicaltrials.gov. NCT numbers are required for all interventional studies. If the NCT number is blank, please notify Annette Kinsella (annettek@uic.edu) This field may be left <u>blank</u> if no NCT number currently exists or if it is not applicable.
Department	Oncology
Title (Regular/ long Title)	SHORT TITLE : Full title (Exact title of protocol). Make sure that the major words are capitalized and that the minor words are lowercase in the full title. Also check that there are no page breaks within the title.
Short Title	The short title entered here populates to other screens within the OnCore application and is displayed in some reports and notifications.
Objectives	Enter the main objective from the protocol to this field. Paste and review for spacing and extra lines and correct/edit as needed.
Phase	Select the phase of the study from the drop-down list. If the study is a pilot study, choose "N/A" as there is a separate field for pilot studies.

<b>Scope</b>	<b>National</b> - Nationwide or international (i.e. cooperative studies) <b>Local</b> - Only at UIC or its affiliates and usually an Investigator Initiated Trial
<b>Age</b>	Select the age group for eligible subjects
<b>Consent at Age of Majority</b>	<b>Blank</b> - For adults <b>Yes</b> - If children should be re-consented near their 18 <sup>th</sup> birthday <b>No</b> - If no re-consent will be required for children when they reach 18 years
<b>Drug Accountability</b>	<b>Yes</b> - The sponsor will supply the drug <b>No</b> - The drugs are standard of care or commercially available <b>N/A</b> - No drugs are involved in the protocol
<b>Investigator Initiated Protocol</b>	<b>Yes</b> - A UIC investigator develops the protocol and UIC is the lead site though it may be sponsored by an industry or a cooperative group. <b>No</b> - For industry protocols, cooperative group protocols, or any other protocol developed by a non-UIC investigator.
<b>Involves Therapy</b>	<b>Yes</b> - Therapeutic, Prevention, Supportive Care type trials <b>No</b> - Registries, Screening, Early Detection and Lab Correlate trials <b>N/A</b> - Chart reviews and Surveys
<b>Exclude Protocol on Web</b>	Check the box if the protocol should <b>NOT</b> show on the UICC website clinical trials list.
<b>Open for Affiliates Only</b>	Check <b>No</b> We will not be using the Affiliates Only component in OnCore.
<b>Summary Accrual Info. Only</b>	Summary accrual is a way to enter accruals without needing to register or add patients though the CRA console. Subject visits cannot be tracked and summary accrual only displays limited information (ie: gender, age, ethnicity, race). Accruals can be grouped for enrollments that share the same demographics when this format is used. <b>No</b> - If interventional <b>Yes</b> - When only summary information of subjects accrued is going to be recorded. This acceptable only for non-interventional studies. *The setting chosen cannot be changed once subjects are accrued to the protocol.
<b>Protocol Type</b>	Select the appropriate protocol type. If there is an NCT# for the study, search the study on clinicaltrials.gov to make sure that the coding there matches the coding selected in OnCore. <b>Basic Science</b> – Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention. <b>Diagnostic</b> – Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition. <b>Health Services Research</b> – Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care. <b>Prevention</b> – Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition. <b>Screening</b> – Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor). <b>Supportive Care</b> – Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant’s health or function. In general, supportive care interventions are not intended to cure a disease. <b>Treatment</b> – Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. <b>Other</b> – Not in other categories

<b>Cancer Control</b>	<p><b>Yes</b> – If cancer control science is being done.  <i>NCI Definition:</i> the conduct of basic and applied research in the behavioral, social, and population sciences to create or enhance interventions that, independently or in combination with biomedical approaches, reduce cancer risk, incidence, morbidity and mortality, and improve quality of life (Cancer Control Program Review Group, 1998—modified).</p> <p><b>No</b> – If cancer control science is not being done</p>
<b>Cancer Prevention</b>	<p><b>Yes</b> - If study involves subjects that do not currently have cancer. Subjects can be at risk of the cancer or remission. Use this field to indicate that the protocol is being used for cancer prevention</p> <p><b>No</b> - Protocol is not being used for cancer prevention</p>
<b>Data Table 4 Report Type</b>	<p>Select the appropriate DT4 type. If there is an NCT# for the study, search the study on <a href="http://clinicaltrials.gov">clinicaltrials.gov</a> to make sure that the coding there matches the coding selected in OnCore.</p> <p><b>Interventional</b> – Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed</p> <p><b>Observational</b> – Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.</p> <p><b>Ancillary or Correlative</b> –</p> <ul style="list-style-type: none"> <li>• <i>Ancillary:</i> Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.</li> <li>• <i>Correlative:</i> Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.</li> </ul> <p><b>Not Applicable</b> – Not in other categories and usually exempted by the PRC (ie: retrospective chart review studies).</p>
<b>Registration Center</b>	<p><b>External</b> - For Industry/Cooperative Group registrations  <b>Cancer Center</b> - For Investigator Initiated or local protocols</p>
<b>Involves Correlates or Companions</b>	<p><b>Yes</b> - If protocol is directly related to another protocol and/or subjects must be registered to both protocols otherwise select <b>No</b></p>
<b>Data Monitoring</b>	<p><b>External</b> - For industry sponsored studies with their own Data &amp; Safety Monitory Board.  <b>DSMC</b> - For Institutional Investigator Initiated Protocols  <b>PI</b> - For retrospective, chart review, or data collection studies</p>

<b>Adjuvant</b>	<b>Yes</b> - If protocol is adjuvant - Indicates that the study drug is enhancing or otherwise affecting the impact of another drug <b>No</b> - If protocol is NOT adjuvant <b>N/A</b> - For chart reviews, survey, etc.
<b>Includes Specimen Banking</b>	Check box if the protocol collects specimen for banking otherwise, leave blank
<b>Companion Study</b>	Indicates that the protocol is a companion to another study.
<b>Multi-site Trial</b>	<b>Yes</b> - If Multi-site <b>No</b> - Protocol will only open at single site
<b>Investigational Drug</b>	<b>Yes</b> - If investigational drug is being used <b>No</b> - If no investigational drug is being used <b>N/A</b> – If not applicable. This is often used for chart reviews, survey, etc.
<b>Precision Trial</b>	<b>Yes</b> - If trial uses precision medicine <b>No</b> - If trial is <b>NOT</b> using precision Medicine
<b>Precision Trial Classification</b>	Only available if <b>Yes</b> is selected for <b>Precision Trial</b> . Leave blank if <b>No</b> is selected. <b>Basket</b> - for trials that allow the study of multiple molecular subpopulations of different tumor or histologic types all within one study. These trials can include highly rare cancers that would be difficult to study in randomized controlled trials, and they might include multiple treatments by which subjects are matched based on gene expression. <b>Umbrella</b> - for trials using a design that focuses on a single tumor type or histology. It involves a group of two or more enrichment designs, or sub-studies, that are connected through a central infrastructure that oversees screening and identification of patients. <b>Target</b> - for trials designed to evaluate treatments targeted at one or two molecular populations in single or multiple disease type. <b>Other Adaptive Trials</b> - for other studies believed to be precision medicine trials based on non-traditional study design not identified above, limited inclusion criteria, and emphasis on patient-centric treatment.
<b>Pilot</b>	<b>Yes</b> – the study is a pilot phase. <b>No</b> - the study is not a pilot phase.
<b>Investigational Device</b>	<b>Yes</b> - If investigational device is being used <b>No</b> - If no investigational device is being used <b>N/A</b> - For chart reviews, survey, etc.
<b>Rare Disease</b>	<b>Yes</b> - If trial is studying rare disease. For AML studies, the Rare Disease Field should always be “yes”. <b>No</b> - If no rare disease is being studied Please reference National Institutes of Health site for a list of rare cancers: <a href="https://rarediseases.info.nih.gov/diseases/diseases-by-category/1/rare-cancers">https://rarediseases.info.nih.gov/diseases/diseases-by-category/1/rare-cancers</a>
<b>CCTS Participation</b>	<b>Yes</b> - If trial is using CCTS services <b>No</b> - if trial is not using CCTS services

<b>Accrual Information</b>	
<b>Protocol Target Accrual</b>	The overall accrual goal for the protocol. Includes accrual from all participating sites
<b>RC Total Accrual Goal (Lower)</b>	The minimum total accrual goal for UIC
<b>RC Total Accrual Goal (Upper)</b>	The maximum total accrual for UIC
<b>RC Annual Accrual Goal</b>	The prospective number of accruals per year for UIC

<b>Affiliate Accrual Goal</b>	The prospective number of accruals for all affiliate institutions (if applicable) Note: If it is an Affiliate Only protocol, the accrual information needs to be filled based on the affiliate's accrual goals
<b>Accrual Duration (Months)</b>	The estimated length of time that the study will be open to accrual

<b>Completion Dates</b>	
<b>Primary Completion Dates (radio dot available to allow actual and anticipated dates)</b>	The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.
<b>Study Completion Dates (radio dot available to allow actual and anticipated dates)</b>	Final date on which data was (or is expected to be) collected

5. Click the **Save** button to save changes up to this point. The submission electronic form will expand to display additional sections and fields.

Click the **Save** button often to save changes while filling in this submission electronic form. When work is saved, the Submitter can log-out of OnCore and complete the submission at a later time without having to start over.

6. Fill in the **Administrative Groups** section of the form as defined below:

<b>Administrative Groups</b>	
<b>Program Areas</b>	If one of the Cancer Center research programs, please elect one of the following <b>Cancer Biology</b> <b>Cancer Prevention and Control</b> <b>Translational Oncology</b> If not one of the Cancer Center Research programs, please select the following <b>ZY non-programmatically aligned</b>
<b>Disease Committee</b>	Please select the disease committee that matches the Disease Team that granted your protocol approval and ensure that it is listed as "primary" by checking the box. OnCore only allows 1 primary Disease Committee, but you may add other non-primary options for reporting purposes.
<b>Management Group</b>	Please select the Management Group affiliated with your protocol. This includes either "CTO- managed" or "Non-CTO-managed" and the appropriate disease group. <ul style="list-style-type: none"> <li>• If the investigator of the study is the lead investigator, make sure that "primary" is assigned to "CTO managed" or "Non-CTO managed".</li> <li>• For multi-site investigator-initiated studies with the UIC PI as the lead PI, "lead site" should be added to management group</li> <li>• For investigator-initiated studies that will be monitored by the UI Cancer Center DSMC, "UICC DSMC Monitoring" should be added as a management group.</li> </ul>

**Remaining Sections for Study Submission:**

7. In the **Disease Sites** section of the submission electronic form, click the **Select** button to choose all the disease sites that are eligible for the protocol from the popup window by checking the appropriate checkboxes and clicking the **Add** button. Please note that it is important to select all the appropriate disease sites as these will trigger the options available when registering a patient to the study.
8. In the **Institution** section of the submission electronic form, click the **Select** button to choose the participating institution(s) from the popup window by checking the appropriate checkboxes and clicking the **Add** button.
9. In the **Sponsor** section of the submission electronic form, click the **Select** button to choose the sponsor and click **Add**. If the Sponsor is not on the list, contact the OnCore team to add the sponsor of the list. Enter the Sponsor Protocol Number. Check the box of the Principal sponsor. If multiple sponsors are involved, it is important to state the primary sponsor, as this will trigger in many reports.
10. In the **Competing Protocols** section of the submission electronic form, list competing protocols by entering their protocol numbers and clicking the **Add** button. If there are no competing protocols check the **No Competing Protocol** checkbox.
11. In the **Documents** section of the submission electronic form, attach the following documents to be included within the submission: Protocol (final/clean version), Disease Team Feasibility Documentation (if applicable), PI NIH Biosketch (if NIH Biosketch is not available a curriculum vitae (CV) may be substituted), a completed Data Safety Monitoring Plan form for interventional studies (and Data Safety Monitoring charter if applicable), a completed protocol summary form for interventional studies, and other supporting documentation. Supporting documentation may include surveys, questionnaires, and other tools that help explain the protocol submitted.
  - For multi-site studies that have already been externally peer reviewed and the lead site is an NCI designated cancer center, the protocol review approval letter from the lead site should be requested and uploaded to the study record.
12. In the **Protocol Staff** section of the submission electronic form, choose the staff involved in the protocol using the **Add** button after each selection. It is required to add a Principal Investigator, submitter, and protocol coordinator (unless the study will not be using a CRC). If the study will be pushed over to Epic, a lead clinical research coordinator and financial coordinator are also required. Please reference the **OnCoreEpic RPE Interface Study Build and Maintenance SOP** for further details.
  - If this study includes the JBVA, add staff as usual, then go to update>edit>switch organization to Jesse Brown or add another role with Jesse Brown as organization. Jesse Brown staff should at minimum include the PI, CRC, and protocol coordinator.
13. In the Signoffs section of the submission electronic form, you can leave this blank as we do not utilize this.
14. When the form is complete, click the **Send** button to send the submission electronic form to the PRC team.
15. The PRC Manager will review the submission for completeness. If it is complete, the protocol will be placed on an agenda. If there are inquiries, a query will be generated, or the PRC team will reach out to the submitter for clarification.

\*If at any time after ePRMS initial submission you need to make updates to the study, you can do so through the Protocols>PC console

**Other sections to update through the PC console:**

16. Priority Score: Required for CTO managed studies that went to a disease team. In the “management” tab, the study must be assigned a score. Please refer to the PRC policy to reference the scoring table.

17. Participating Institution checkbox: In the “institution” tab, click the institution hyperlink. Navigate to the “study sites” tab. Make sure that the “study participant?” field is checked off if applicable.

18. Task list: Required for CTO managed studies. In the “status” tab, navigate to the “task lists” tab. Make sure that task lists are associated for UIC and/or the VA. The task lists with the most recent versions/dates should be used (UIC-Version 4, JBVA- Version 2). If needed, please refer to the **UICC Setting Up Task Lists in OnCore 2021R3 SOP** for instructions on setting up task lists.

*If your study will be interfaced with Epic please see SOPs:*

OnCore\_Epic RPE Interface Study Build and Maintenance

OnCore\_Epic RPE Interface Subject Workflow