UNIVERSITY OF ILLINOIS CANCER CENTER
Bench to Community

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:

Protocol Details	
Library	Oncology
Review Type	Full (Default)
Protocol Number	Sponsor protocol number is suggested. 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
Department	Oncology
Title (Regular/ long Title)	Exact title of protocol
Short Title	Contains abbreviated version (100 characters maximum) of the protocol title. The short title entered here populates to other screens within the OnCore application and is displayed in some reports.
Objectives	Enter the main objective from the protocol to this field. Review and paste for spacing and extra lines and correct/edit as needed.
Phase	Select the phase of the study from the drop down list
Scope	**National -** Nationwide or international **Local -** Only at UIC or its affiliates and usually an Investigator Initiated Trial
Age	Select the age group for eligible subjects

Consent at Age of Majority	**Blank -** For adults **Yes -** If children should be re-consented near their 18th birthday **No -** If no re-consent will be required for children when they reach 18 years
Drug Accountability	**Yes -** The sponsor will supply the drug **No -** The drugs are standard of care or commercially available **N/A -** No drugs are involved in the protocol
Investigator Initiated Protocol	**Yes -** A UIC investigator develops the protocol though it may be sponsored by an industry or a cooperative group. If study is developed by an investigator of an affiliate site. **No -** Exclusively for industry and cooperative group protocols
Involves Therapy	**Yes -** Therapeutic, Prevention, Supportive Care type trials **No -** Registries, Screening, Early Detection and Lab Correlate trials **N/A -** Chart reviews and Surveys
Exclude Protocol on Web	Check the box if the protocol should **NOT** show on the Cancer Center website. Check the box for chart reviews and survey protocols
Open for Affiliates Only	**Yes -** If an Affiliate is the only participant in the study (E.g. of affiliates – Jesse white, Regions Hospital, Rush) **No -** Open for UIC, UIC and Affiliates
Summary Accrual Info. Only	**No -** If interventional **Yes -** When only summary information of subjects accrued is going to be recorded. E.g. For chart reviews and survey type protocols
Protocol Type	Select the appropriate protocol type **Basic Science –** Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention. **Diagnostic –** Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition. **Health Services Research –** Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care. **Prevention –** Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition. **Screening –** 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). **Supportive Care –** 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.

	Treatment – Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. **Other –** Not in other categories
Cancer Control	**Yes –** If cancer control science is being done. *NCI Definition:* 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). **No –** If cancer control science is not being done
Cancer Prevention	**Yes -** 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 **No -** Protocol is not being used for cancer prevention
Data Table 4 Report Type	**Interventional –** 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 **Observational –** 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. **Ancillary or Correlative –** • *Ancillary:* 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. • *Correlative:* 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. **Not Applicable –** Not in other categories

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Registration Center	**External -** For Industry/Cooperative Group registrations **Cancer Center -** For Investigator Initiated or local protocols
Involves Correlates or Companions	**Yes -** If protocol is directly related to another protocol and/or subjects must be registered to both protocols otherwise select No
Data Monitoring	**External -** For Clinical Research Organization (CRO) or Sponsor **DSMC -** For Institutional Investigator Initiated Protocols **PI -** For retrospective, chart review, data collection studies
Adjuvant	**Yes -** If protocol is adjuvant - Indicates that the study drug is enhancing or otherwise affecting the impact of another drug **No -** If protocol is NOT adjuvant **N/A -** For chart reviews, survey, etc.
Includes Specimen Banking	Check box if the protocol collets specimen for banking otherwise, leave blank
Companion Study	Indicates that the protocol is a companion to another study.
Multi-site Trial	**Yes -** If Multi-site **No -** Protocol will only open at single site
Investigational Drug	**Yes -** If investigational drug is being used **No -** If no investigational drug is being used **N/A -** For chart reviews, survey, etc.
Precision Trial	**Yes -** If trial uses precision medicine **No -** If trial is **NOT** using precision Medicine
Precision Trial Classification	Only available if **Yes** is selected for **Precision Trial** **Basket -** 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. **Umbrella -** 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. **Target -** for trials designed to evaluate treatments targeted at one or two molecular populations in single or multiple disease type. **Other Adaptive Trials -** 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.
Investigational Device	**Yes -** If investigational device is being used **No -** If no investigational device is being used **N/A -** For chart reviews, survey, etc.

Accrual Information	
Protocol Target Accrual	The overall accrual goal for the protocol. Includes accrual from all participating sites
RC Total Accrual Goal (Lower)	The lower total accrual goal for UIC
RC Total Accrual Goal (Upper)	The upper total accrual for UIC
RC Annual Accrual Goal	The prospective number accruals per year
Affiliate Accrual Goal	The prospective number of accruals for all affiliate institutions Note: If it is an Affiliate Only protocol, the accrual information needs to be filled based on the affiliate's accrual goals
Accrual Duration (Months)	The estimated length of time that the study will be open to accrual

Completion Dates	
Primary Completion Dates (radio dot available to allow actual and anticipated dates)	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.
Study Completion Dates (radio dot available to allow actual and anticipated dates)	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 Submitted 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:

Administrative Groups	
Program Areas	If part of the Cancer Center research programs please elect one of the following Cancer Biology Cancer Prevention and Control Translational Oncology ZY non-programmatically aligned
Disease Committee	Please select the disease affiliated with your protocol
Management Group	Please select the Management Group affiliated with your protocol

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 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, and other supporting documentation. Supporting documentation can include surveys, questioners and other tools that help explain the protocol submitted.
12. In the **Protocol Staff** section of the submission electronic form, choose the following staff involved in the protocol using the **Add** button after each selection. It is required to add a Principal Investigator, Protocol Coordinator and Submitter.
13. Click the **Save** button
14. When the form is complete, click the **Send** button to send the submission electronic form to the PRC Manager.
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.