UFHCC
Protocol Creation Guidance

OnCore®
Clinical Trials Management System
Purpose:
This section covers setting up a new protocol.

In This Section:
- Setting up basic protocol information
- Submitting the Completed ePRMS Submission

Further Reference:
For a comprehensive description of the material and contexts covered in this section, please refer to the Protocol Administration Tutorial documentation on the online OnCore Learning Portal.
SESSION UP BASIC PROTOCOL INFORMATION

From ePRMS Submission Console, select ‘Initial Review’ from vertical menu bar.

PROTOCOL DETAILS

Fields marked with an asterisk (*) are mandatory fields for all interventional cancer studies. All other fields can be considered optional/informational fields that you can use at your discretion.

<table>
<thead>
<tr>
<th>OnCore Field</th>
<th>Definition / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Library*</td>
<td>Select ‘Oncology’</td>
</tr>
<tr>
<td>Review Type*</td>
<td>Select the review type that corresponds with the submission in accordance with the SRMC Policies and Procedures Manual. Review type may be full, expedited or administrative (exempt).</td>
</tr>
<tr>
<td>Protocol No.*</td>
<td>A unique, protocol identifier. OnCore does not allow for any spaces within the Protocol No. field.</td>
</tr>
<tr>
<td>NCT Number*</td>
<td>Enter the NCT ID from clinicaltrials.gov. Enter the entire number including the ‘NCT’. If the number is pending, enter ‘TBD’. Please update the field once the number becomes available.</td>
</tr>
<tr>
<td>Department*</td>
<td>Select the department which is submitting the protocol. In general the department should reflect who is managing the financial/contractual component of the study which may or may not be the PI’s home department. Shouldn’t it be MD-Cancer Center Clinical Trials?</td>
</tr>
<tr>
<td>Organizational Unit*</td>
<td>Select ‘Cancer Center’ if not pre-selected.</td>
</tr>
<tr>
<td>Title*</td>
<td>Full title of the protocol. This should match the official title noted within the ClinicalTrials.gov entry for applicable studies.</td>
</tr>
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</tr>
<tr>
<td>Short Title*</td>
<td>An abbreviated version of the protocol title. When possible, Include the phase, drug or treatment and disease. An attempt should be made to match the short title noted within the ClinicalTrials.gov entry for applicable studies. This is the only title used on the NCI Data Table 4 report.</td>
</tr>
<tr>
<td>Objectives*</td>
<td>The Objectives field is used to populate clinical trial listings on the public website and other documentation. As a default, the ‘Purpose’ field on the clinicaltrials.gov listing should be used to populate this field. If the ClinicalTrials.gov listing is not available, a brief description of the trial will be entered as an alternative. At a minimum, the primary study objective should be included. This field should be reviewed carefully for word spacing and insertion of extra lines. Please correct as needed.</td>
</tr>
<tr>
<td>Phase*</td>
<td>For Interventional studies acceptable phases include: pilot, feasibility, 0, I, II, III, IV, or combinations such as I/II. For epidemiologic, cancer control/behavioral, observational, ancillary, correlative, or other biological studies, indicate ‘N/A.’</td>
</tr>
<tr>
<td>Scope*</td>
<td>Select local or national. Local protocols are only open at the cancer center or its affiliates.</td>
</tr>
<tr>
<td>Age*</td>
<td>Select the appropriate age category.</td>
</tr>
<tr>
<td>Consent at Age of Majority*</td>
<td>Select ‘Yes’ if the protocol includes children and if these children will be required to re-consent on or after their 18th birthday. Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>Drug Accountability*</td>
<td>Select ‘Yes’ if drugs are being supplied by the study. Select ‘No’ if only standard of care/commercial supply drugs are used. Select ‘N/A’ if no drugs are used in the protocol.</td>
</tr>
<tr>
<td>Investigator Initiated Protocol? *</td>
<td>Select ‘Yes’ if the protocol was written by a UF investigator, regardless of sponsorship/funding source. Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>Involves Therapy</td>
<td>Select ‘Yes’ if the protocol uses a therapeutic intervention (e.g. Treatment or Supportive Care study). Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>Exclude Protocol on Web</td>
<td>Check this box if the protocol SHOULD NOT appear in listings of available clinical trials (e.g. public website, published clinical trial listings, etc.). In general, all interventional trials should be available on the web; however it may be appropriate to exclude others.</td>
</tr>
<tr>
<td>Open for Affiliates Only</td>
<td>Select ‘Yes’ if the protocol will be opened for accrual at affiliate sites but not at the cancer center. Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>Summary Accrual Info. Only*</td>
<td>Select ‘No’ when individual subjects will be registered to the protocol. ‘No’ must be selected for all interventional trials at a minimum. Select ‘Yes’ when only aggregate, summary subject data will be collected for a protocol.</td>
</tr>
<tr>
<td>Protocol Type*</td>
<td>Select the appropriate protocol type from the list. Consult the CCSG data guide for specific definitions of each type. (<a href="https://cancercenters.cancer.gov/Documents/CCSGDataGuidev3-508C.pdf">https://cancercenters.cancer.gov/Documents/CCSGDataGuidev3-508C.pdf</a>)</td>
</tr>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cancer Control</td>
<td>Select ‘Yes’ for protocols that are 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. Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>Cancer Prevention</td>
<td>Select ‘Yes’ for protocols with interventions that keep a cancerous process from ever developing and may include health counseling and education, environmental controls, and product safety. Prevention also includes interventions leading to the discovery and control of cancerous or precancerous processes while localized (e.g. screening and early detection). Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>Data Table 4 Report Type*</td>
<td>Select the appropriate report type from the list. Consult the CCSG data guide for specific definitions of each type. (<a href="https://cancercenters.cancer.gov/Documents/CCSGDataGuidev3-508C.pdf">https://cancercenters.cancer.gov/Documents/CCSGDataGuidev3-508C.pdf</a>)</td>
</tr>
<tr>
<td>Registration Center*</td>
<td>Select ‘Institution’ if UF will be responsible for ClinicalTrials.gov registration and reporting. Otherwise select ‘Sponsor’ or ‘Other’ as applicable.</td>
</tr>
<tr>
<td>Involves Correlates or Companions</td>
<td>Select ‘Yes’ if this protocol will have designated companion studies in OnCore or if you will be tracking correlative specimens for this protocol in OnCore. Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>Data Monitoring*</td>
<td>Select the party responsible for monitoring the protocol data. All Phase III studies should have DSMB oversight. UFHCC Interventional IITs will be monitored by DISC if they do not have an external DSMP in place.</td>
</tr>
<tr>
<td>Adjuvant</td>
<td>Select ‘Yes’ if study drug is enhancing or otherwise affecting the impact of another drug or treatment.</td>
</tr>
<tr>
<td>Includes Specimen Banking?</td>
<td>Select ‘Yes’ if you will be tracking protocol specimens in the OnCore BioSpecimen Management system (BSM). It also indicates that consent records are tracked in the Specimen Collection Console instead of Subject Console &gt; Consent. Otherwise, select ‘No’.</td>
</tr>
<tr>
<td>UF CRC Participation</td>
<td>Select ‘Yes’ if UF CRC resources are being used in the protocol. Otherwise, select ‘No’.</td>
</tr>
</tbody>
</table>
| Multi-site Trial*                  | Select ‘Yes’ if this study recruits from two or more distinct study sites. For protocols in the Oncology library, this field affects Data Table 4 reporting as follows:  
  • If marked as 'Yes', the protocol is considered multi-site on the Data Table 4 report, regardless of whether multiple institutions are listed in the PC Console > Institution tab.  
  • If marked as 'No', the protocol is not considered multi-site on the Data Table 4 report, regardless of whether additional institutions are listed in the PC Console > Institution tab.  
  • If left blank, the protocol is determined as multi-site based on whether more than one institution is listed in the PC Console > Institution tab. |
| Investigational Drug*              | Select ‘Yes’ if an investigational drug is being used in the protocol. Otherwise, select ‘No’.                                                                                                                                 |
| Precision Trial                    | Select ‘Yes’ for trials that incorporate biomarker defined targets and molecularly selective agents.                                                                                                                      |
### OnCore Field Definition / Instructions

**Precision Trial Classification**
- **Basket** - for trials that allow the study of multiple molecular subpopulations of different tumor or histologic types all within one study.
- **Umbrella** - for trials using a design that focuses on a single tumor type or histology.
- **Targeted** - 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.

### Accrual Information

<table>
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<tbody>
<tr>
<td>Protocol Target Accrual*</td>
<td>Enter the total number of subjects to be enrolled in the protocol at all sites.</td>
</tr>
<tr>
<td>RC Total Accrual Goal (Lower) *</td>
<td>Enter the expected number of subjects to be enrolled at the Cancer Center. This number will inform SRMC initial and annual reviews.</td>
</tr>
<tr>
<td>RC Total Accrual Goal (Upper) *</td>
<td>Enter the maximum number of subjects that may be enrolled at the Cancer Center. This number should account for consented screen failures at the Center.</td>
</tr>
<tr>
<td>RC Annual Accrual Goal*</td>
<td>Enter the expected number of subjects to be enrolled at the Cancer Center each year. This figure should be based off of the CC Total Accrual Goal (Lower) and Accrual Duration.</td>
</tr>
<tr>
<td>Affiliate Accrual Goal</td>
<td>Enter the total expected number of accruals at all Cancer Center affiliates running the protocol.</td>
</tr>
<tr>
<td>Accrual Duration (Months)*</td>
<td>Enter the estimated number of months it will take for enrollment to be completed for the protocol.</td>
</tr>
</tbody>
</table>

### Completion Dates

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<tbody>
<tr>
<td>Primary Completion Date</td>
<td>Enter the actual or estimated date that the final subject is examined or receives an intervention for the purposes of final collection of data for the primary outcome. Refer to ClinicalTrials.gov for the anticipated Primary Completion Date.</td>
</tr>
<tr>
<td>Study Completion Date</td>
<td>Enter the date on which data was (or is expected to be) collected. Refer to ClinicalTrials.gov for the anticipated Study Completion Date.</td>
</tr>
</tbody>
</table>

After entering these fields, click the [Save] button and the protocol will be created and saved in the system.
ADMINISTRATIVE GROUPS

PROGRAM AREA*: 
Programs are defined by the individual cancer centers in which research takes place. This is a required field for Data Table 4 reporting. The Program Area selection is driven by the Principal Investigator’s affiliation with a Cancer Center Program.

1. Select the [Select] button to select a Program Area.
2. Check the box next to the appropriate Program Area and then click the [Add] button. For PIs that are not affiliated with a Cancer Center Program select ‘N/A’. If you do not know which program your PI is affiliated with, please contact the Cancer Center’s Research Program Administrator for guidance (ResearchAdmin@cancer.ufl.edu).

DISEASE SITE GROUP*: 
Groups defined by the Cancer Center that define the patient population served by the studies.

1. Select the [Select] button to select the Disease Site Group(s).
2. Check the box(es) for the appropriate Disease Site Group(s) and then click the [Add] button.
3. Once added, select which group is the Primary and then click the [Submit] button. For protocols that serve more than one Disease Site Group, select all included groups and note the Primary group. The Experimental Therapeutics Group should be selected as the Primary for studies that involve multiple DSGs and novel therapeutics.

MANAGEMENT GROUP*: 
Groups within the Cancer Center that manage the protocols.

1. Select the [Select] button to see the browse results for Management Group.
2. Check the box next to the appropriate Management Group and then click the [Add] button.
3. Once added, check the Primary checkbox and click the [Submit] button. Additional Management Groups may be added as appropriate in the same way (only one group can be marked Primary).

DISEASE SITES* 
Disease Sites are used to identify the disease types that are allowed by your protocol. These disease sites are defined by the NCI and cannot be changed. Choose all disease sites included by your study’s eligibility criteria. What about those protocols list as “advanced solid tumors” or something equally general?

1. Click the [Select] button to see the browse results for Disease Sites.
2. Check the boxes next to the Disease Sites for your protocol and then click the [Add] button.
3. Repeat this process until all applicable disease sites have been added.
INSTITUTIONS*

Identify all study sites and study locations for the protocol.

ADD THE CANCER CENTER INSTITUTION

1. Click the [Select] button to see the browse results for Institutions.
2. Select the checkbox for the ‘University of Florida’.
3. Select the [Add] button to add the institution to the protocol.
4. By default, all Study Sites will be selected under the ‘Participant’ column. De-select any Study Sites not participating in the protocol.
5. Select the [Save] button to save your selections.

SELECT PARTICIPATING STUDY SITES

1. Using the same steps as above, use the [Select] button to add additional sites which are participating as affiliates or as sub-sites to the UF Health Cancer Center.
2. Select the [Add] button to add the additional institution(s) to the protocol.
3. Update the list of Study Sites for each institution and select the [Save] button to save your selections.

SPONSORS*

All sponsors must be listed in the Sponsors section. This includes any organization that provides drugs, funding, NCI credits or other support for the study. Studies where UF is the responsible party should always have UF noted as the primary sponsor.

1. Click the [Select] button to see the browse results for Sponsors.
2. Select the checkbox by each sponsor for the study.
3. Select the [Add] button to add the sponsor(s).
4. Once the sponsor has been added, record the Sponsor Protocol No. (aka. Sponsor protocol ID) and select the ‘Principal’ checkbox next to the study’s principal sponsor. For protocols that meet the criteria to be included on the NCI Data Table 4 Report, the Principal Sponsor indicator will be used to determine the sponsor number to use on the report. At least one sponsor must be marked as the Principal Sponsor for the protocol to be included in the report. If more than one sponsor is marked as Principal, a warning message will appear upon clicking Submit, indicating potential problems with NCI Data Table 4 accrual reporting.
5. The specific name of the financial sponsor for the clinical research study must also be noted if different from the Principal Sponsor. To designate the funding source add the sponsor and select the role link. There you will be able to check ‘Funding Source’. Note that funding source does not indicate which group is providing payment to the site but rather which group’s funds are being used to support the trial.
6. Other roles such as ‘Agent Source’, ‘Clinical Research Organization (CRO)’, ‘Data Analysis’, and
‘Design’ should also be assigned to each sponsor as applicable.

7. Select the [Save] button to save your selection.

COMPETING PROTOCOLS*

All studies which compete for the same subject populations must be identified and a recruitment priority must be established. Please refer to the SRMC Manual for additional information on study prioritization.

If a protocol has a competing trial:
1. Enter the Protocol No. and select the ‘Browse’ icon to select the study.
2. Repeat step 1 above to add additional competing studies.

If the protocol does not have any competing protocols:
1. Select the ‘No Competing Protocol?’ checkbox and select the [Save] button.

DOCUMENTS*

The Documents section can be used to add relevant protocol documents for review by the SRMC and for access by protocol staff. These documents can include PRMC submission documents, protocols, investigational brochures, eligibility documents, etc. Please refer to the SRMC Manual to determine which documents should be uploaded for your study.

ADDING AN ATTACHMENT

1. Select the ‘Type’ dropdown and choose the appropriate document type from the list.
2. Enter the document Description, Version Date, and Expiration Date in the appropriate fields.
3. Select the [Choose File] button to locate the file on your local computer or network harddrive.
4. Select the [Add] button to attach the document to the study.
5. Repeat steps 1 – 4 above to add additional documents.

PROTOCOL STAFF*

ADDING INDIVIDUAL STAFF TO A PROTOCOL

1. Begin typing the staff member’s name in the Staff Name search box and select the hyperlink for your choice.
2. Select a staff role from the Role dropdown.
3. Select the [Add] button.
4. Repeat the above steps until all protocol staff members have been added.
5. At a minimum, the PI, Submitter and Primary Study Coordinator or IRB Coordinator should be identified.
**ADDING A STUDY TEAM TO A PROTOCOL**

You can copy part or all of a study team from another study and add them to your protocol. This is useful when the study staff are the same or similar across protocols.

1. Select the [Select Team] button.
2. Enter the Protocol Number or Sponsor Protocol Number in the Protocol No. field and select the hyperlink for your choice.
3. Select the [Show Team] button.
4. From the resulting staff list, check one or more staff members that you wish to add.
5. Select the [Submit] button to add the selected staff to your protocol.

**WEBSITE CONTACT INFORMATION**

To list a contact name on the cancer center website for a given study, that person must be identified on the Protocol Staff list with a Role of ‘Study Site Contact’. This role assignment would be in addition to their primary role on the study (if applicable).

**ADDITIONAL SUBMISSION DETAILS**

The following details are required before a study can be submitted for PRMC review:

**PC CONSOLE > MAIN > DETAILS**

**INVESTIGATIONAL DEVICE**

1. Select ‘Yes’ if the protocol involves an IDE device.
2. Select ‘No’ if the protocol involves an approved device.
3. Otherwise, select ‘N/A’.

**PC CONSOLE > MAIN > MANAGEMENT**

**PRIORITY SCORE**

Insert the priority score (1 – 15) that corresponds to the protocol’s originator and study type as outlined in the SRMC Manual.
1. Select the [Add] button to attach the protocol to all appropriate disease sections. If you do not have permissions to attach the protocol to a flowchart, please contact the SRMC Coordinator (UFHCC-SRMC@ufl.edu).

PC CONSOLE > MAIN > SPONSOR TAB

SPONSOR DETAILS

Select [Edit] next to each sponsor type to clarify their role in the project.

DATA TABLE 4 REPORT SETTING

The Principal Sponsor's default Sponsor Type may be overridden for users with the appropriate privilege. The override is applied only for this protocol and will change the way the protocol is categorized on the Data Table 4 reports. If you need to override the sponsor type and do not have appropriate privileges, please contact the SRMC Coordinator.

- **National**: NCI National Clinical Trials Network (NCTN) and other NIH-Supported National Trial Networks

- **Externally Peer-Reviewed**: R01s, SPORES, U01s, P01s, CTEP or any other clinical research study mechanism supported by the NIH or organizations on this list: http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf

- **Institutional**: In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results. It is acceptable for industry or other entities to provide support but the trial should clearly be the intellectual product of the center investigator. The category may also include institutional studies authored and implemented by investigators at another Center in which your Center is participating. Multi-institutional studies authored and implemented by investigators at your Center (Note: National and externally peer-reviewed studies should be listed with those categories, not at Institutional studies).

- **Industrial**: A pharmaceutical company controls the design and implementation of these clinical research studies.

- **Other should not be selected for any protocol**
IDE INFORMATION

1. Select ‘Yes’, ‘No’ or ‘N/A’ from the Investigational Drug and Device dropdowns and select the appropriate responses.
2. If ‘Yes’ is selected, select the [Add] button on the Details block.
3. Enter the ID, Holder Type, Holder Name and any other relevant details and then select the ‘Save’ hyperlink.

REGULATORY ITEMS*

1. Click on the hyperlink for each participating institution to designate the protocol institution IRB and applicable laboratory sites.
2. Select [Add] for each time to select the applicable items from the drop down list.

REGULATORY ITEMS

1. Create or update the Annotations by clicking on “Update” at top or bottom right hand corner. There are multiple fields that may be updated.
2. Questions 1-5 are optional to assist with Regulatory processing.
3. IRB-Approved for HealthStreet?
   - Select ‘Yes’ if the protocol is approved to use HealthStreet as a Recruitment Resource. If a study is approved by WIRB, for the Cancer Center, HealthStreet is “Yes” unless the study is a companion study or is not seeking active patients. If a study is approved by NCI CIRB, HealthStreet will always be “No”
   - Select ‘No’ if this is not IRB approved, the protocol recruits only from a companion study, or the protocol is approved using the NCI CIRB.
• Otherwise, select ‘N/A’.

3. “Study Sites”: This question is what feeds the 1572 sites and IDS pharmacy. Select all that are applicable to that trial. This information can be used to create the 1572 document via the FDA 1572 Report found under the Reports tab [Administrative section].

4. Most questions on the annotations page are there in case the study team wishes to utilize them; and often will be updated throughout the startup process.

## SUBMITTING THE COMPLETED EPRMS SUBMISSION

After all required information has been entered, submitted can navigate to the Reports tab > SRMC Submissions to run the SRMC Submission Form report.

This Form must be signed by the PI and Management Group leader, scanned and uploaded into Documents section within the ePRMS console. The protocol can then be submitted electronically for review by the SRMC. To make the submission, select protocol from the Active list in the ePRMS Submission Console. Select the [Send] button to submit the protocol to the ePRMS Coordinator. Please refer to the SRMC Policies and Procedures Manual for additional details.

After review and approval by the PRMC committee, the protocol status will be PRMC APPROVAL.