SRC Submission instructions and guidelines

1. Go to https://uahs-oncore-prod.forteresearchapps.com/forte-platform-web/login to login to OnCore with your UA Net ID. *(For Oncore access contact: OncoreSupport@email.arizona.edu)*
2. Click on "Menu" → "ePRMS" → "Submission Console."
3. Under Create Submission, click on Initial Review.
   a. An SRC number will generate after the submission is saved. To initially save a submission, all that is required is the "Library" and "Protocol Type." Select the Library and Protocol Type, hit save, and then continue with the SRC submission process.
   b. Click "Save" to save the application. DO NOT hit "Submit" until all items have been entered and checked for completion.
4. Enter the data in the indicated fields as described below:

Create Initial Submission	
Library	• "**Oncology**" for cancer studies • "**General Medicine**" for non-cancer studies
Review Type	• "Full" for initial submissions. • "Admin" for exempt studies (cooperative group, externally peer-reviewed, or retrospective). • If uncertain, SRC coordinator will update appropriately
Protocol Number	• Enter the SRC number until a local IRB number is obtained or leave blank. • Note that after saving the ePRMS submission, an SRC number will be generated as the Submission ID number.
NCT Number	• Enter the NCT number as it appears on https://clinicaltrials.gov/ • If no NCT number is available, leave this field blank.
Department	• The department is used as a means of reporting and granting access to specific types of trials. Access to trials will be limited, depending on the selected department. Select the appropriate department from the drop-down. • "**Cancer Center Division**" – always select if the study is being run by UA Cancer Center. • "**Asthma/Airway Disease Rsch Ctr**" – Asthma/Airway Disease Research Center • "**COM PHX**" – College of Medicine in Phoenix • "**COM TUC**" – College of Medicine in Tucson • "**Sarver Heart Center**" – Sarver Heart Center
Organizational Unit	• Pre-populated with your assigned unit. For UACC, this should say "Cancer Center."

Title	• Copy the full title from the protocol. • **Do not use all capital letters or** hard returns in the title.
Short Title	• Create a short title from the full title using the guidance below. • Note: There is a 100 character limit. <u>Short Title Instructions</u>: • Change "versus", "v", or other versions of this to "vs." • Change "Phase" to "Ph." • Change Phase digits (ex: "2" or "3") to roman numerals (ex: "II" or "III") • Change/add cooperative group numbers at the beginning as follows "S1203: short title" • For SWOG, change to "S"; for ECOG, change to "E"; for GOG, keep "GOG"; for CALGB, keep "CALGB"; for RTOG, keep "RTOG" (to match CTSU protocol numbers) • Capitalize each word, except for articles (ex: E2906: Ph. III Efficacy of Celecoxib, Selenium, or Celecoxib + Selenium on Adenomatous Polyp Recurrence") • Add a space after commas • Change "plus" to "+" • Change "and" to "&" • Change "with" to "w/" • Change "without" to "w/o" • Change "with or without" to "+/-" • Periods at the end of every abbreviation
Objectives	• Copy the objectives as listed in the protocol including any primary, secondary, and exploratory objectives.
Phase	• Select the phase from the dropdown menu of "I, I/II, II, II/III, III, IV, Pilot, N/A, V". • For epidemiologic, cancer control, behavioral, observational, ancillary, correlative, or other biological studies, select "N/A".
Scope	• "Local" if IIT or only local site • "National" for multi-site
Age	• "Adults" if subjects are only 18 years and older • "Children" if subjects are under 18 years old • "Both" if subjects include adults and children
Consent at age of majority	• This is only available when the "Children" or "Both" age is selected. • "Yes" if children should be re-consented near their 18th birthday • "No" if children should not be re-consented near their 18th birthday

Drug Accountability	• "Yes" if an investigational product (study drug) will be received, stored, and dispensed. Used for most industry-sponsored studies. • "No" if investigational product is not involved. • "N/A"
Investigator Initiated Protocol	• "Yes" if protocol is written by the PI. • "No" if protocol is not written by the PI. Most industry studies and cooperative group studies.
Involves Therapy	• "Yes" if study involves therapy or treatment • "No" if study does not involve therapy. • "N/A"
Exclude Protocol on Web	• Check box only for emergency use/single patient studies or if expressly told not to include on website.
Open for Affiliates Only	• "Yes" only if open at affiliate sites such as UACC-Orange Grove only. • "No" in most cases where study is open at the main sites.
Summary Accrual Info Only	• "Yes" if only accrual information for the study is to be entered, not detailed patient information, for example for a registry study. • "No" if individual subject data will be entered
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. • "**Other**": Not in other categories. Retrospective studies. • "**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. Note: This equates to therapeutic trials in previous versions of the guidelines. *Most UACC trials fall in to this category.

Cancer Control	• "Yes" if study is for cancer control. • "No" if not
Cancer Prevention	• "Yes" if study is for cancer prevention. • "No" if not
Data Table 4 Report Type	• "**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. • "**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. Most cases. • "**Not Applicable**": Retrospective studies • "**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.
Registration Center	• "AZCC" for all studies done at UACC. • "External" if not UACC.
Involves Correlates or Companions	• "Yes" if cooperative group or involves companion studies. • "No" if not
Data Monitoring	• "**DSMB w/o QAQC**": trial where the UACC DSMB (i.e. the oversight entity) is the DSMB of record but the UACC QA/QC program is not the monitoring entity of record. For example, a prevention trial. • "**DSMB w/ QAQC**": trial where the UACC DSMB (i.e. the oversight entity) is the DSMB of record and the UACC QA/QC program is the monitoring entity of record. For example, most IIT studies.

	• "**External**": trial where the UACC DSMB (i.e. the oversight entity) is not the DSMB of record and the UACC QA/QC program is not the monitoring entity of record. For example, most industry sponsored studies. • "**Internal (Not UACC DSMB)**": trial that has an internal (i.e. not provided by industry) DSMB (i.e. the oversight entity) that is not the UACC DSMB. For example, prevention trials that use the Prevention Consortium as their oversight entity of record.
Adjuvant	• "Yes" if adjuvant is in the study title. This means second line therapy or a therapy applied after the initial treatment, especially to suppress secondary tumor formation. • "No" if adjuvant is not in the study title. First line therapy or other line of therapy. • "N/A"
Includes Specimen Banking	• Check box if specimen banking is involved. • Leave blank if not.
Companion Study	• Check box if study involves a companion study. • Leave blank if study is not a companion study.
Multi-site Trial	• "Yes" if there are multiple institutions involved. Appears in the Data Table 4 report. • "No" if there are not multiple institutions involved. Appears in the Data Table 4 report.
Investigational Drug	• "Yes" if the study involves investigational drugs. • "No" if the study does not involve investigational drugs or if all drugs involved are approved. • "N/A"
Precision Trial	• "Yes" if it qualifies as one of the classifications below. • "No" if it does not qualify as one of the classifications below.
Precision Trial Classification	• "**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. • Will be blank if Precision Trial is selected as "No".
Pilot	• "Yes" if the study is a pilot study. • "No" if the study is not a pilot study.
Investigational Device	• This will only populate after SRC approves the submission. Update the main page under the PC Console page as needed. • "Yes" if the study involves an investigational device. Rarely. • "No" if the study does not involve an investigational device or if all devices involved are approved. • "N/A" if no device is involved.
Rare Disease	• "Yes" if the study is for a rare disease. • "No" if the study is not for a rare disease. Most UACC studies will be "No."
GCRC Participation	• "Yes" if using CATS research facility. General Clinical Research Center.
Accrual Information	
Not Applicable	• Check box only if there is the study has unlimited accrual goals or accrual is not applicable, as in the case of retrospective chart review.
Protocol Target Accrual	• The number of subjects expected to accrue to the protocol – across all sites. • For most studies, this is the expected sample size listed in the protocol.
RC Total Accrual Goal (Lower)	• RC = Research Center • The minimum number of subjects to accrue at this cancer center (for interventional studies, this refers to the number of subjects who will go On Treatment). • **RC Total Accrual Goal (Lower)= Annual Accrual Goal x Duration of accrual (in years).** Example: If the study is open for 18 months, and you anticipate enrolling 3 patients per year, then the lower accrual goal should be $\frac{3\ patients}{1\ year} \times \frac{1\ year}{12\ months} \times \frac{18\ months}{1} = 4.5 \rightarrow 4\ patients$ • This number drives reporting functionality in OnCore and must be entered accurately.
RC Total Accrual Goal (Upper)	• The upper goal is the maximum number of patients the study can support locally– based on the contractual or budgetary limit. • This number can be the same as RC total accrual goal (lower)

RC Annual Accrual Goal	• The estimated number of subjects that will accrue each year at this cancer center. • Studies that do not meet their annual accrual goal may be considered underperforming.
Affiliate Accrual Goal	• The estimated number of subjects that will accrue at the Affiliates of this cancer center (e.g. affiliate institutions, VA, etc.). • When the cancer center has no affiliates, this field can be left blank.
Accrual Duration (Months)	• The estimated number of months the protocol will be open to accrual. • This number should match up with the lower accrual goal and the annual accrual goal. See above equation for example. • When an exact duration is unknown, a best estimate should be used. • The duration may be modified during the study, as unforeseen circumstances often result in extensions of the study duration. • This field refers to the time period for accrual, not long-term follow up.
Completion Dates	
Primary Completion Date:	• Date that the study is anticipated to close to accrual. Can be found in the protocol or on clinicaltrials.gov. • Select “anticipated”.
Study Completion Date:	• Date that the study is anticipated to have all data collection complete, follow-up complete, and ready to close and conclude at the IRB. • Select “anticipated”. • Can be left blank if unknown.
Administrative Groups	
Program Areas	• Each research trial will be assigned to cancer center program based upon the science of the research trial (as of 11/13/2015). Previously this was assigned based on the affiliation of the PI. • If the research trial does not clearly fit within a cancer center program, the research trial will be assigned to the program of the primary principal investigator. • Be sure to check the box for primary. • “Cancer Biology” • “Cancer Imaging” • “Cancer Prevention and Control” • “Non-AZCC Member” • “Non-Programmatically Aligned” • “Therapeutic Development”: most UACC studies. • “Unknown”

Oncology Group	• Select primary disease group from dropdown list. This is the usually team that will carry out the study. • Be sure to check the box for primary. • Can add additional groups if applicable, as long as only one group is the “Primary” group. • “Any”: Any Site • “BMT”: Bone Marrow Transplant • “BREAST”: Breast Cancer • “CUTONC”: Cutaneous Oncology • “GI”: Gastrointestinal • “GYN”: Gynecologic Malignancy • “HN”: Head and Neck • “HEMA”: Hematological Malignancy Other • “LUNG”: Lung • “LYMPH”: Lymphoma • “MELANOMA”: Melanoma • “PEDONC”: Pediatric Oncology • “PHASEI”: Phase I • “PREV”: Prevention • “BRAIN”: Primary Brain Cancer • “PGR”: Prostate/GU/Renal • “RADONC”: Radiation Oncology • “SARCOMA”: Sarcoma • “SURGONC”: Surgical Oncology
Management Group	• Select primary disease team from dropdown list. This is the team that will carry out the study. • Be sure to check the box for primary. • Can add additional groups if applicable, as long as only one group is the “Primary” group. • “BMT/Leukemia” • “Banner Financial Group” • “Breast Cancer” • “COM Phoenix” • “Central Nervous System” • “Childrens Oncology Group” • “Cutaneous Oncology” • “Dignity Financial Group” • “Gastrointestinal” • “Genitourinary/Renal” • “Gynecologic Oncology” • “Gynecological Oncology Group” • “Head and Neck”

	• "Lung" • "Lymphoma" • "Melanoma" • "Non-Cancer Trial" • "Not Disease Team Affiliated" • "Pediatric Oncology" • "Phase I" • "Precision Medicine" • "Prevention" • "Radiation Oncology" • "Sarcoma" • "Skin Cancer Institute" • "Southwest Oncology Group" • "Supportive Care" • "UACC-Phoenix"
Disease Sites	• Select primary disease site(s).
Institutions	• Select institution from list. • This defines which protocol an individual user may see. • Always select "University of Arizona Health Sciences" as the institution. • Consult with PI/disease team to determine where patients will be accrued. • Check all participating sites. Most common UACC sites are listed below. Although patients may be seen at different facilities, only check those sites where patients may be enrolled. • "BUMC – North Clinics": outpatient clinic (3838 N. Campbell Ave) • "BUMC – Orange Grove": clinic at Orange Grove location. • "BUMC – Phoenix": Banner facility in Phoenix • "BUMC – South": South campus hospital (2800 E. Ajo Way). Do not check unless patient is enrolling here. • "BUMC – Tucson": main campus hospital (1625 N. Campbell Ave) • "Dignity Health St. Joseph": Dignity's hospital in Phoenix for General Medicine and legacy data only. • "UACC-Phoenix": UACC facility in Phoenix • "University of Arizona Health Sciences": UACC do NOT check this as a research site. It is the institution, but should not be checked as a site for the research. • May see a checkbox "Research Center IRB?" This should be checked if UACC is the IRB of record for other sites (ex. multi-center IITs, where UACC is the coordinating center). Otherwise, leave blank.

Sponsors	• Select sponsor from list. For cooperative group trials, select the lead cooperative group (i.e. SWOG, COG, or NRG; not Alliance, GOG, ECOG, RTOG, etc.). As of 06Oct2016, we are only main members of SWOG, COG, and NRG. This means that if we have an ECOG or Alliance trial, for example, we can only enroll in those studies through our SWOG affiliation. • Enter sponsor number/protocol number. • Be sure to check the box for principal. • Contact Oncore Support if Sponsor not on list
Competing Protocols	• Check box for "No Competing Protocol?" • If there is a competing protocol, identify which protocol competes by adding the IRB numbers into OnCore.

1. Upload the following documents:
    a. Signed/approved disease team approval (if applicable)
    b. IRB submission draft (required for retrospective studies)
    c. List of research personnel
    d. Protocol
    e. Investigator's Brochure (for drug studies)
2. Add study staff individually, or select a team from another study to add staff. Be sure to designate the Principal Investigator, Primary CRC, Primary IRB Coordinator, and Primary RN (as appropriate).
3. Submit to SRC.
    a. The submission cannot be edited once it has been submitted; any subsequent changes will have to be made by the regulatory manager or committees coordinator.
    b. SRC will send an automatic email to confirm submission.
    c. A similar notification will be sent when an approval notice has been uploaded.

Timelines for SRC review and approval:

Full committee review: submission will be assigned to the next available agenda. Committee meets on the 2nd Friday and 4th Wednesday of each month. Decision letters are sent within a week of the meeting.

Exempt/administrative review: submissions are reviewed by the Chair upon receipt and decision letters are sent within a week

Questions?: Contact UACC-SRC@uacc.arizona.edu