PROTOCOL TEMPLATE

Row Header Definitions

Definitions are provided below for user reference when completing and submitting an OnCore Accrual Template. The row headers listed here appear in Column A of the Protocol Template tab.

Term	Definition
Current Date	This is the date the form is filled out.
UArizona IRB Number	This is the number provided by the IRB.
NCT Number	If appropriate, please provide the ClinicalTrials.gov number.
Principal Investigator Name	This is the Principal Investigator for the study.
Title	This is the official title for the study. (Please do not use nicknames.)
Sponsor Name	This is the research sponsor. If this is an Investigator Initiated trial, the sponsor should be listed as the University of Arizona.
Sponsor Number	This is the number that the sponsor has assigned to the study.
Investigator Initiated (Y or N)	An Investigator Initiated study is the original idea of the Principal Investigator (as opposed to a sponsor).
Phase	Phases include pilot, 0, I, II, III, IV, or combinations such as I/II.
IRB Initial Approval Date	This is the initial approval date by the IRB.
Open to Accrual Date	This is the date you can start accruing subjects to a study.
Last IRB Review	This is the date the protocol was last submitted for IRB approval.
Last IRB Approval Date	This is the date the protocol received its current IRB approval.

Current IRB Expiration Date	This is the protocol's expiration date.
Closed to Accrual Date	This is the date that you stop accruing subjects to a study with IRB approval. However, you may still work on data analysis or publications after this.
IRB Study Closure Date	This is the date the study concluded at the IRB. No more data analysis or publications are pending.
Protocol Type	**Basic Science (BAS)**: Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention. **COVID**: Protocol designed to examine preventive interventions or treatments for COVID-19 risk factors, infection, symptoms, and/or related health conditions. **Diagnostic (DIA)**: Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition. **Health Services Research (HSR)**: Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care. **Prevention (PRE)**: Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition. **Registry**: Protocol that applies observational study methods to standardized data to evaluate outcomes for a specific population, as defined by a particular disease, condition, exposure, or other factor. **Screening (SCR)**: 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 (SUP)**: Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease. **Treatment (TRE)**: Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. **Other (OTH)**: Protocol not in other categories.

Clinical Research Category (Oncology Only)	**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.
Target Accrual Goal	The number of subjects in the trial or study that are expected to be enrolled during the entire period of the study and are needed to evaluate the research question, and the expected distribution by sex/gender, race, and ethnicity based on the prevalence of the disease or outcome of interest in the population and study characteristics.
Annual Accrual Goal	The number of subjects in the trial or study that are expected to be enrolled each year as part of the Target Accrual Goal.