Protocol Life Cycle Subcommittee
OnCore Instructions
Dose Escalation/ Dose Expansion Studies

Determining Accrual Targets
Accrual targets are determined for studies at the time of Disease Aligned Research Team (DART) Protocol Review. The accrual information is noted in the DART Protocol Review Form and in the Details Section of the Main Tab in the protocol record within the Clinical Trials Management System, OnCore.

OnCore:

DART Protocol Review Form:
If the study includes multiple phases, indicate how many subjects you expect to enroll in each phase.

Multi-phase Studies
Multi-phase studies that include dose escalation and dose expansion will be recorded as multi-phase studies in the Details Section of the Main Tab of OnCore. If the study includes multiple phases, the team will indicate in which phase they will participate on the DART Protocol Review Form.

OnCore:

Pick the appropriate Phase from the drop-down list. Typical options include IB/II or I-II.

DART Protocol Review Form:
If the study includes multiple phases, indicate which phase(s) Yale will be participating in.
Accrual Target
The accrual target for each phase will be noted in OnCore and within the DART Protocol Review Form for multi-phase studies that include dose escalation and dose expansion. The RC Total Accrual Goal (Lower) will be used to note the Dose Escalation accrual target. After dose escalation is complete, the RC Total Accrual Goal (Lower) may be changed for accrual monitoring purposes by the study team. If the dose escalation and dose expansion target enrollment changes during the conduct of the study, the targets will be updated in OnCore following IRB of record approval (if required). The dose escalation and dose expansion accrual targets will be noted in the DART Protocol Review Form.

OnCore:

DART Protocol Review Form:
If the study includes multiple phases, indicate how many subjects you expect to enroll in each phase.

Suspending Arms/ Phases in OnCore
The Phases are noted in the Details Section of the Treatment tab in OnCore. The study team will ensure all relevant phases are noted at the time of OnCore Calendar Review before the study opens to accrual and when revisions are made due to an amendment.

Individual phases and arms will be suspended in the Details Section of the Treatment tab rather than at the Study Status level during dose escalation as enrollment is temporarily held by the sponsor. To avoid non-compliance, it is recommended that consent document(s) and study conduct document(s) that relate to suspended portion(s) of the study be temporarily removed from the Attachments Section of the Documents/ Info tab in OnCore. The phase/ arm suspension will be lifted when the sponsor allows enrollment to resume.

When a phase permanently closes to further accrual, i.e., the dose escalation period ends, the dose escalation phase(s) will be suspended in the Details Section of the Treatment tab. Consent document(s) and study conduct document(s) that relate to the permanently closed portion(s) of the study will be removed from the Attachments Section of the Documents/ Info tab in OnCore.
Study-wide Suspensions in OnCore
If at any time, enrollment to all enrolling parts of a study are suspended for any reason, the Status Section of the Status tab in OnCore will be updated to reflect a status of suspended. Comments may be added to provide a rationale for the suspension.

Accrual Monitoring by Protocol Life Cycle Subcommittee
The Protocol Life Cycle Subcommittee (PLCS) will consider accrual rates during dose escalation compared to dose expansion. It is expected that accrual will progress more slowly during dose escalation. For these considerations to be made by the PLCS, the study team must adhere to the requirements listed above. The PLCS will apply the Accrual Monitoring Policy to all studies.