UFHealth CANCER CENTER

University of Florida Health Cancer Center Scientific Review and Monitoring Committee (SRMC)

Summary of Changes Form

OCR Number:	
Protocol Title:	
Principal Investigator:	

The modification impacts the following study or scientific elements *(Check all that apply):*

☐	**Design**	Addition of a new protocol arm, changing any objectives or endpoints, or the statistical analysis.
☐	**Eligibility**	Change in eligibility based on inclusion and/or exclusion criteria. (Does not include administrative clarifications to eligibility).
☐	**Therapy/ Intervention**	Removing or adding protocol interventions that were not in the original study design; Includes changes to any protocol drug including dose, administration, route, pre-medications, dose modification, or preparation.
☐	**Risk/Benefit**	Change to the risk/benefit ratio that significantly affects the scientific value. For instance, if a more effective treatment option is available.
☐	**Addition of Study Sites**	Addition of one or more study sub-sites (Specific for Investigator-Initiated Trials).
☐	**Subject Accrual Goals**	Change to the study accrual goals by increasing or decreasing the overall number of subjects the study anticipates to accrue (including screen fails or expanding pilot studies).
☐	**PI Change**	Change of the Principal Investigator for the study.

Provide a list or brief summary of changes noted above:

Provide a brief scientific rationale for the proposed changes. If no changes to scientific merit, please indicate "N/A" (for example, PI change only):

Additional Comments:

Principal Investigator Signature

Date