

SOM CRA Options Guide

1. This study is industry initiated, offset 10%

You would choose this option if it is an industry initiated study. Because the IFR mechanism doesn't lend itself to accrual based research activity as is the case with clinical trials, this mechanism is proposed as an option to facilitate your research. In the case of industry sponsored studies by selecting this box, 10% of the invoiced study income will be transferred to a Clinical Research Offset Account managed by your department. It is the expectation of the School of Medicine that funds in this account will be used by the department to further support clinical research efforts of its faculty. Zero percent effort is not acceptable.

2. A) This study is investigator initiated or a Federal/Federal flow through trial, or PCORI study, offset 5%

You would choose this option if it is an investigator initiated study, or Federal/Federal flow through trial, or PCORI study. Because the IFR mechanism doesn't lend itself to accrual based research activity as is the case with clinical trials, this mechanism is proposed as an option to facilitate your research. In the case of investigator initiated studies by selecting this box, 5% of the invoiced study income will be transferred to a Clinical Research Offset Account managed by your department. It is the expectation of the School of Medicine that funds in this account will be used by the department to further support clinical research efforts of its faculty. Zero percent effort is not acceptable. **Please note that if a fixed amount is budgeted by the sponsor & a separate amount is for subject payments select the box option below (B: N/A Investigator/s effort will be offset via IFR or charged directly to the award).*

B) N/A Investigator/s effort will be offset via IFR or charged directly to the award

Wherein the investigator feels confident that accruals for this study will be at or near maximum, the investigator may choose to IFR a fixed % of time. If an NIH award functions as a trial/ evaluative test but is funded as a grant.

3. This agreement is unfunded

You would select this option if the agreement is unfunded and there is no money involved. You would place your effort under 7b in MyResearch and this effort would count towards the SOM 5% Cost Share Cap. If you are listing your effort as 0% (unfunded) you must provide what exactly your role is in the study and what you will be doing in the budget justification, along with the RFA/RFP (to justify the 0% effort).

4. The terms of the Offset Agreement do not apply, as the effort on this study is to be cost shared within the limits of the SOM 5% cost share cap. This is consistent with all State faculty participants involved with this study.

This effort would count towards the SOM 5% Cost Share Cap.

- 5. *The terms of the Offset Agreement do not apply, as the effort on this study is to be cost shared. This cost share will not count towards the SOM 5% cost share cap.***

This option is to be used for Registries and Cooperative Oncology Group Studies*

* If the Cooperative agreement group study is unfunded then you would submit the SOM CRA with the *This agreement is unfunded* box checked off and would also need to upload the RFA to MyResearch that states it is unfunded. *