



School of Medicine Clinical Research Offset Agreement

Policies and Procedures

May 2015

Scope:

Both Industry initiated and Investigator initiated drug or device clinical trial agreements.

Purpose:

The School of Medicine Clinical Research Offset Agreement represents an alternative mechanism to offset faculty participation/effort on clinical trials (excluding federal, and federal flow through), Investigators will be required to allow the Office of the VP for Research to transfer a percentage of all direct costs received (excluding the IRB fees and the Office of Clinical Trials fee) into a Departmental Clinical Research Offset award. For industry initiated trial agreements, the offset amount will be 10%, and for investigator initiated trial agreements the offset amount will be 5%.

Procedures:

- Investigator must include a SOM Clinical Research Offset Agreement with every clinical trial COEUS proposal. Separate forms are required if investigator effort is offset with a different mechanism, other than the SOM Offset Agreement (see note below). Submittals of COEUS proposal without the SOM Clinical Research Offset Agreement will result in an automatic rejection of the proposal without benefit of SOM review.
- The Office of the VP for Research will transfer the offset into the appropriate Departmental Clinical Research Award as cash is received.
- The Departmental Clinical Research Offset award will be used at the discretion of the Department Chair to further enhance the departmental research infrastructure.

NOTE: SOM Offset Agreement is not applicable where the investigator's effort is offset via IFR form or charged directly to the award.