



School of Medicine Clinical Research Offset Agreement

Policies and Procedures

Scope:

Both Industry initiated and Investigator initiated drug or device clinical trial agreements. This agreement is not limited to human studies. Applicable animal trials may be required to complete a CRA (determined on a case by case basis).

Purpose:

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

Procedures:

- Investigator must include a SOM Clinical Research Offset Agreement with every clinical trial or evaluative testing study. Submittals of MyResearch 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 account as cash is received through invoicing of the study by Grants Management.
- The Departmental Clinical Research Offset award account will be used at the discretion of the Department Chair, but it is expected to further enhance the departmental research infrastructure in support of future research work.