





- Obtain and utilize the appropriate research order form for that particular ancillary department by contacting the ancillary department directly. Contact information for all ancillary departments as well as research order forms for Shands at UF Cardio-Pulmonary Services, GI- Endoscopy & EEG, Radiology, and Surgery/Anesthesia can be accessed under their respective sections [here](#).
- Check the box at the top of the research order form titled, “**NO R99#, BUT STUDY-FUNDED SERVICES (including participant specific) ARE UNEXPECTED or URGENT,**” enter the name of the Principal Investigator; Study Coordinator Name and Phone Number; Study Name; Department to Be Invoiced and PO Box #; Study Billing Contact and Phone#. This information must also be given to the scheduler for scheduled services to ensure that Shands Admissions creates the account correctly.
- Obtain a COS from the appropriate ancillary department(s), complete a [Study Registration Form](#), and submit to the RAC office as soon as possible following the rendering of the service(s). The [RAC office](#) will send you the Discounted Pricing Worksheet from Shands PFS and/or FGP and the R99 number for the study within 10 business days of RAC approval.
- Reconcile your tracking log with [Shands PFS](#) and [FGP](#) monthly, as needed.

Contracts & Grants (C&G) Expenditure Close-out Policy for Industry-Sponsored Clinical Trials. The University of Florida Contracts & Grants (C&G) Office has issued an [Expenditure and Close-Out Policy for Industry Sponsored Clinical Trials](#). Prior to sending a signed Closeout Memo to C&G, please send your completed [Participant Service Tracking Log](#) to the Research Administration & Compliance (RAC) Office. Should you need any assistance completing this log, please contact RAC at 273-5946. For any questions regarding the Expenditure and Close-Out Policy, you may contact C&G directly at 392-1235.

Budget Appropriate Investigator Effort.  
<http://www.med.ufl.edu/research/rac/new/policies.shtml>

Colleges within the UF Health Science Center must be sure to budget appropriate investigator effort reimbursement in contracts for clinical research funded by industry sponsors. This includes all time associated with the study including administrative, oversight and clinical. This does not apply, however, if the investigator is reimbursed by a third party.

PI Salary Support Policy for Industry-Sponsored Trials. Some pharmaceutical companies are now claiming they "don't pay for PI salaries" when negotiating clinical trial contracts. The COM has an unwritten policy that "appropriate PI time and effort" should be included in any clinical trial contract. Contracts are reviewed based on this standard. Several units have indicated that these same companies have said they respond to a written University or College policy. The proposed policy has been set forth, as follows:

**“It is the policy of the University of Florida Health Center that its Colleges budget appropriate investigator effort reimbursement in contracts for clinical research funded by industry sponsors. This would include all time associated with the trial including administrative, oversight, and clinical time, except in the case where the effort is reimbursed by a third party.”**

Pooled Fringe Benefit Rates. The Department of Health and Human Services (DHHS) has approved eight (8) pooled fringe benefit rates proposed by UF for 2009-2010. These go into effect on all contracts and grants effective June 26, 2009. Existing grants will be required to absorb the cost of increases in fringe benefits reflected in these new rates; and research grants, instead of the departments, will now be responsible for payout costs when a faculty member terminates. A fringe benefit calculator reflecting these new pooled rates by employee category is available in the myUFL grants system and also at the HRS website Benefits section (<http://hr.ufl.edu/benefits/fringepool/faq.asp>).

Informed Consent Form (ICF). The informed consent form templates on the [IRB-01 website](#) have recently been revised for clarity. The changes within the section titled, “What are the Financial Issues If You Participate?” are as follows:

- Question # 14
  - The Costs Template that was originally embedded in hidden text has been moved to a [separate document](#), where the language can now be copied and pasted into the unprotected area on the ICF.
  - An informational piece was added to question #14 to assist researchers in identifying when they will need to have their research reviewed by the RAC Office.
- Question # 16
  - The Injury Related Costs Template has been moved to a [separate document](#), where the language can be copied and pasted into the unprotected area on the ICF.
- Revised WIRB templates are pending, so please continue to check the WIRB section of the UF IRB website (<http://irb.ufl.edu/wirb/>) when preparing an ICF.





