

Regulatory Services

<http://icts.wustl.edu/cores/rsc.aspx>

Below is a breakdown of our levels of service (all of which are cumulative).

Level 1 Services (Consultation)

Level 1 services include discussion of protocol, procedures required, budget expectations, & enrollment.

We can provide template tools for developing protocol, informed consent form and/or per patient budgets.

Level 2 Services

Level 2 services include revision/review previously developed protocol, informed consent form, and/or per patient budget.

Level 3 Services

Level 3 services include budget preparation/negotiation and initial IRB paperwork preparation & ongoing IRB support. Also a complete Regulatory binder will be created.

Level 4 Services

Level 4 services include initial IND/IDE preparation and annual IND/IDE reporting consultations with PI.

For information regarding the Levels of Service and their costs, please contact
Phyllis Klein at 314-747-4289.

**If ICTS pilot funded investigator or KL2 scholar, first 10 hours will be fully subsidized*

Coordinator Services

Our team of highly skilled study coordinators can serve as a resource for PIs who need assistance in coordinating some or all elements of a given study. The coordinators are experienced in clinical drug trials, device trials, pediatric studies, government funded trials and PI-initiated studies. They are all fully trained in the informed consent process, procedure scheduling, data and specimen collection, lab processing and shipment, and data entry. This team includes clinical research coordinators, registered nurses as well as ACRP-certified coordinators.

Our program is designed for PIs to 'pay as you go' for coordinator services, in order to remove the burden for PIs and their departments who would otherwise take on the total annual financial costs and logistics required to hire their own coordinators. Coordinator assignments include a primary coordinator and a back-up coordinator who can work with the PI and their staff to successfully conduct trials. We are committed to subject enrollment, subject retention, patient safety and data integrity.

For information regarding Coordinator Services please contact

Teresa Arb at 314-747-1217