Announcement of a Master Services Agreement with Charles River Laboratories for GLP-Compliant Studies and Related Services

So as to facilitate the clinical translation efforts of our faculty, the Office of Research Protections, in cooperation with the University's Purchasing Services Department, has recently executed a Master Services Agreement with Charles River Laboratories (CRL) for the conduct of Good Laboratory Practice (GLP) compliant, non-clinical safety (i.e., pharmacology/toxicology or biocompatibility) studies.

This existence of this Master Agreement eliminates the requirement for a separate contract for each project involving the purchase of GLP-compliant studies performed by CRL. In addition, transfers of unique (i.e., developed at the University) laboratory animal models (e.g., "knock-out" models) and test articles between the University and CRL for the purpose of the GLP studies performed under this Master Agreement are exempt from the requirement for a Material Transfer Agreement (MTA).

Under this Master Services Agreement, investigators involved in the clinical translation of experimental drugs and devices have no-cost access to CRL's Scientific Advisory Services for assistance in the design of appropriate GLP-compliant, non-clinical safety studies; to include respective cost estimates. Having this information is important for the preparation of FDA submissions (Pre-IND meetings, Q-submission meetings, IND and IDE applications) and for identifying funding sources for these required studies. As the largest provider of GLP study services in the country, access to CRL's Scientific Advisory Services will permit faculty engagement with a wide breadth of respective expertise. It is thus anticipated that this relationship will address the majority of the related needs of our faculty involved in the clinical translation process.

Procedures:

- For investigators seeking access to CRL's Scientific Advisory Services for assistance in the preliminary design of GLP-compliant studies:

    1) Email (o3is@pitt.edu) the Office for Investigator-Sponsored IND and IDE Support (Office of Research Protections). This office will have you complete a CRL Program/Science Review form and will put you in contact with the appropriate CRL representative.

- For the purchase of GLP-compliant studies performed by CRL:

    1) The investigator's responsible department requests a corresponding Statement of Work (SOW) from CRL
    2) CRL provides a quote for the SOW and, in the SOW, CRL specifically refers to the Master Services Agreement (MSA) as the governing terms for the quote.
    3) The department signs the SOW, verifying that the MSA has been properly cited.
    4) The department submits either a "non-catalog" form or a "blanket/standing order" form (i.e., if there will be recurring services wherein CRL will bill multiple times) to the Panther Express System. The signed SOW is attached to either form as an "External Attachment". Note: there is no requirement to submit a Directed or Sole Source Justification Form (DSSIJF) or a Certificate of Liability Insurance (COLI).
    5) If the value of the SOW is less than $10,000, the department approves the requisition internally. Once the requisition is approved, a Panther Express purchase order is generated and sent to CRL along with the attached, signed SOW.
    6) If the value of the SOW is greater than $10,000, the department creates a requisition for routing to the Purchasing Services, which reviews and approves the requisition. A Panther Express purchase order is generated and sent to CRL along with the attached, signed SOW.
    7) Upon receipt of the invoice, the department submits it to Payment Processing with the purchase order number clearly visible on the invoice.

If you have questions related to this Master Services Agreement or the respective purchasing procedures, please contact the Office for Research Protections (byates@pitt.edu) or, if applicable, the University's Purchasing Services Department.