Office of Science and Research
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To: All Clinical Researchers

From: James Holahan, Director, Clinical Research Support Unit (CRSU) James Holahan
Helen Panageas, Director, Institutional Review Board (IRB) Helen Panageas

Re: OSR Administrative Fees – Industry Supported Projects

The NYU Langone Health retains Institutional Review Boards (IRB) and an IRB operational team to support the function of the IRB's. The IRB's function include the initial and ongoing review of research studies to assess the safety, efficacy, benefits, adverse reactions, other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring or preventive measures and ensures the research is in compliance with federal regulations and institutional policies and procedures. IRB Operations facilitates the review process of human subjects research at NYU Langone and our affiliates. The IRB Operations team provides professional guidance to the research community and supports researchers in submitting to an IRB. The IRB Operations Unit includes the External Review Unit which facilitates the institutional clearance process for all human subjects research that is undergoing external IRB review, ensuring compliance with NYU Langone policies.

The Clinical Research Support Unit (CRSU) provides centralized guidance and support to the entire NYU Langone Health clinical research community. The Unit charges a standard benchmarked rate per study for start-up, amendment, and close-out activities to all Industry Sponsors and Commercial Agencies for all clinical research studies. The fees collected are to strictly cover the administrative cost for activities leading to the activation and ongoing operational support of the clinical research study on behalf of the Institution. The CRSU fee does not encompass any compliance inquiries or other work performed by the office and is not shared with the investigator.

Specific activities performed by CRSU include, but are not limited, site feasibility, protocol review, reimbursement analysis, internal budget development and approval, CTMS study set-up, administrative data auditing and monitoring, research billing compliance and support, sponsor invoicing, financial account reconciliation and medical center technical & professional service centers, response to sponsor inquires, CMS device submissions, portfolio activity analysis, subject recruitment feasibility, referral and registration guidance, study staff orientation, system/process training, procedure development and support.

Office of Science and Research Fee table:

Start up Fees	**Amendment Fees**	**Annual Fees**	**Closure Fees**
All industry-funded clinical research budgets are assessed a non-refundable Office of Science and Research fee of **$8,500.00** at study start-up. This covers the central office operations at study start-up: • Initial NYU (local) IRB Review **($3,500)** • Clinical Research Support Unit (CRSU) Administrative Start-up management **($5,000)**	IRB Amendment Reviews **($1,500)** CRSU Amendment (For Sponsor Initiated Amendments) **($1,000)**	IRB Continuation Reviews **($1,500)** CRSU Annual Financial Administrative Fee **($1,000)**	IRB Closure Review **($500)** CRSU Closure (For Study Reconciliation) **($1,500)**
Other as applicable: • External IRB (central IRB) one time administrative fee **($2,500)** • CRSU Centers for Medicare & Medicaid Services (CMS) Device Approval Submission Process **($2,000)** • CRSU Commercial Vendor & Service Provider Arrangements (Per Arrangement) **($500)** • Data & Material Use Project Start-up **($500)** • Subsite Engagement & Start-up per site **($1,000)**			