UCSF Helen Diller Family Comprehensive Cancer Center

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Dear Sponsor:

Thank you for choosing the Helen Diller Family Comprehensive Cancer Center at the University of California San Francisco (HDFCCC UCSF) for your research project. I am enclosing our standard non-refundable fee schedule (Table 1) for all trials that are done through our Clinical Research Support Office (CRSO). Our goal is to ensure the smooth, efficient, and compliant operation of your clinical research study while delivering the highest quality data. These fees are retained by our institution for essential costs and are not included in the Investigator compensation.

The 2022 fees represent the fair market value of any normal activities performed in our region and are non-negotiable. Fees are reviewed annually and subject to change. The previous fee schedule was set in 2019 and the 2022 fee schedule reflects salary increases over the past 3 years. All fees detailed below are inclusive of institutional overhead (33%).

Additional non-negotiable institutional charges such as Institutional Review Board (IRB), pharmacy, and coverage analysis are set by the University of California San Francisco and are not negotiated by the HDFCCC. Details on these costs can be found in your study budget.

Please let us know if you have any further questions.

Regards,

DocuSigned by:
Thomas Cunningham
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A Comprehensive Cancer Center Designated by the National Cancer Institute

Table 1: 2022 HDFCCC Non-Refundable Fee Schedule

Fee	Billing Period	Explanation of Costs	Cost
CRSO Start-Up Fee	Contract execution	The CRSO is comprised of highly specialized, experienced personnel working in regulatory affairs, protocol activation and management. Our specialists work together to guide industry sponsored trials through all the process and procedures required to activate and maintain the study while adhering to all applicable laws, regulations and UC Policies. The HDFCCC Start-up fee includes but is not limited to the following: - CRSO regulatory document preparation and submission to the UCSF IRB and IRB of record (if applicable) - Review and modification of consent form to meet local/institutional requirements - Scientific review – as per NCI mandate, all protocols are reviewed by our scientific review committee to ensure scientific relevance and available resources - Electronic regulatory file maintenance – one-time fee for study set-up and maintenance of an electronic filing system to house all electronic regulatory files. At the HDFCCC we use the Complion platform for electronic regulatory filing. Use of the Complion platform allows sponsors the capability of remote monitoring of regulatory files. - Administrative oversight to ensure proper study conduct and operations	$7,793
CRSO Regulatory Maintenance Fee	Annually	Management of oncology clinical trials requires continuous maintenance through the life of the trial. The CRSO regulatory annual maintenance fee covers the cost of research staff time and effort necessary to maintain your clinical trial including but not limited to: - Regulatory renewal document preparation including IRB continuing reviews and all amendments - Scientific review of all amendments Maintenance of essential documents necessary for adherence to UCSF requirements and all other applicable governing regulations	$2,997
Close out	Study close-out (IRB close-out)	Study staff are required to perform additional tasks at the end of the trial to close-out the study, while meeting all UCSF and regulatory obligations. The Close-out fee covers staff effort for the following: - Regulatory and financial close-out - Close-out visit with sponsor	$4,256
SAE fee	Variable (billed only if event occurs)	All Serious Adverse Events are reported in an expedited fashion by the study team. The SAE fee covers effort to report initial SAEs and follow-up/discharge reports to all required parties including the sponsor and IRB as applicable	$465

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Notary Events	Signature	Timestamp

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Signing Complete	Security Checked	10/12/2022 1:43:26 PM
Completed	Security Checked	10/12/2022 1:43:26 PM

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