UCSF Helen Diller Family Comprehensive Cancer Center

Clinical Research Support Office

BRCA Research Center
Breast Oncology
Cutaneous Oncology
Early Phase Therapeutics
Radiation Oncology
Thoracic Oncology
Head and Neck Cancer
Cancer Immunotherapy Program
Hematopoietic Malignancies
Gastrointestinal Medical Oncology
Genitourinary Medical Oncology
Gynecology Oncology
Pediatric Oncology

August 16, 2019

Dear Sponsor,

The purpose of this Helen Diller Family Comprehensive Cancer Center (HDFCCC) letter is to describe restrictions to study-specific cost language in informed consent forms (ICFs) that are presented to HDFCCC research participants for both UCSF internally- and externally-sponsored studies.

Costs discussed in HDFCCC ICFs must be limited to standard cost language mandated by UCSF IRB. Any mention of costs in the ICF beyond this required cost language is considered additional and therefore, prohibited. Particularly, costs and/or billing specifics for study-specific items must be excluded from the ICF; considered non-negotiable. Cost language permitted is as follows:

Are there any costs to me for taking part in this study?

- **For studies where sponsor pays all costs:** *No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.*

- **For studies where subjects may be responsible for some costs:** *Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.*

This requirement abides by UCSF Institutional Review Board (IRB) policy and therefore, University of California Office of the President (UCOP), and will ensure proper billing for sponsors and study participants.

Thank you for your understanding,

DocuSigned by:
Charalambos Andreadis
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Charalambos Andreadis, MD
Medical Director, Clinical Research Support Office
Helen Diller Family Comprehensive Cancer Center