

August 2, 2022

To Whom It May Concern:

This is to outline scientific review requirements for the UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC).

The HDFCCC is under mandate from the National Cancer Institute to triage all clinical research projects pertaining to cancer, whether interventional or noninterventional. The NCI expects the Protocol Review and Monitoring Committee (PRMC), our centralized scientific review committee, and its associated Site Committees to provide formal scientific review on all clinical research conducted at the HDFCCC and its affiliates studying **patients with cancer, patients at risk for cancer, or providers of care to cancer patients**, with rare exceptions, and to do so *prior* to IRB approval.

For studies that fall under the Cancer Center's purview, there are 3 levels of review: full committee review, expedited review, and exempt. In general, interventional trials, whether testing new drug/device interventions or behavioral interventions, require full committee review. Cooperative group studies, selected studies that have already received certain types of peer review, and many epidemiology, imaging or diagnostic studies may be eligible for expedited review. Chart review studies and noninterventional studies (molecular, epidemiology, imaging, etc.) exposing patients only to minimal risk may be exempt – exempt studies *still* require submission to PRMC for formal exemption.

Here are steps you can take to facilitate this review process:

- You may either refer to the [PRMC Review Policy](#) for review levels, or email your IRB Study Application (or protocol document if available) to [PRMC](#) for review level assessment.
- Obtain an OnCore account (if you don't have one already). Email OnCore@ucsf.edu to request training on how to use the ePRMS Submission Console, PC Console, and Subject/CRA Console. See <https://cancer.ucsf.edu/clinical-research/prmc> for more info.
- Be prepared to submit to an [HDFCCC Site Committee](#) for first-stage review if required (depends on review level – if uncertain, contact [PRMC](#)). If full committee or expedited review is warranted, the Site Committee will expect to be provided with **a complete protocol which includes all Cancer Center required components** (if writing a UCSF investigator-initiated protocol, see [Step 1](#) for templates; if submitting a protocol from another institution or sponsor, use the protocol provided).
- Submit your project to the PRMC via the ePRMS Submission Console in OnCore. If you have any questions at this juncture, please see the PRMC Submission and Approval section of HDFCCC' [Wiki](#), or contact [PRMC](#).

Please do not hesitate to reach out with further questions.

Sincerely,

DocuSigned by:

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