

Cancer and Tobacco Control Site Committee to support Interventional Clinical Trials.

Q: Why do we have Site Committees?

A: The NCI requires oversight of all cancer clinical trials. Interventional clinical trials, whether therapeutic or non-therapeutic, undergo scientific peer review and prioritization, as well as monitoring for timely accrual. Observational and ancillary/correlative studies require prioritization and monitoring. The UCSF Cancer Center achieves this through our Protocol Review and Monitoring System (PRMS). At UCSF this is a two-tiered process, in which the first level of review happens at the site committee level for scientific relevance and prioritization, and secondly at the center-wide Protocol Review and Monitoring Committee (PRC, soon to be known as the PRMC). One of the main functions of site committees is to provide the subject-matter expertise in the scientific review of these studies.

Q: Does every trial have to undergo the same level of review?

A: No. There are several levels of scientific review: full review, expedited review and exempt.

Full scientific review is required for **interventional clinical trials**. Broadly speaking, these are trials in which a patient undergoes a procedure, process or treatment that normally wouldn't be undertaken. Example of interventional trials include therapeutics or supportive care interventions that are being studied, imaging, blood draws, biopsies. **Expedited review** (described in the answer to the next question) is undertaken for studies originating from Cooperative Groups or other cancer centers with a fully approved PRMS, some NIH peer-reviewed studies, and certain imaging, diagnostic, epidemiologic, and molecular research studies. Examples of clinical trials or studies that are **exempt** from Site Committee review are chart reviews, data collection, population studies, outcome studies, questionnaires and surveys, archival tissue acquisition.

Q: What if my study has already undergone peer review at the NIH or NCI?

A: Interventional studies that have already undergone full peer review at the NIH generally don't require extensive re-review, but would need to be prioritized and undergo expedited review, which consists of a single reviewer plus sign-off by the Site Committee Chair/Co-Chair. These studies also undergo expedited review at the PRC.

Q: Will the requirement for site committee review affect my grant submission?

A: No. Studies and grants are still submitted to the reviewing agency in the same way as you do now. Prior Site Committee approval is not needed.

Q: Is this a new requirement?

A: No. It is an NCI requirement that every interventional clinical trial in the cancer center undergo review in a site committee followed by PRC review. This is not a new requirement. In the past, we have had very few interventional trials in cancer control, and many were submitted through disease-specific site committees. However, with the development of a new program in Cancer Control which will develop its own portfolio of clinical trials, and greater scrutiny expected of us, all cancer control interventional trials will be required to go through

this review process. The IRB will not approve interventional cancer trials without evidence of PRC review.

Q: Isn't this just an extra step that will slow down the activation of my trial?

A: No. In general site committees do not slow down the activation of trials, because they are comprised of your peers, who are committed to a rapid, transparent process. We also expect a relatively small number of trials going through this site committee. In addition, studies that have already undergone NIH or equivalent peer review currently are eligible for expedited review and are not held up. Furthermore, many investigators throughout the cancer center have found the site committee review process to be hugely helpful in identifying potential problems with the study, in clarifying aims, and in leading to cleaner, leaner, more efficient trials, that in the long run lead to a faster completion.

Q: How does the process work?

A: Your study can be submitted for review to the site committee administrator, Kaya Balke (kaya.balke@ucsf.edu). Kaya will collect all necessary documents from you, and put your study on the agenda for the site committee. The site committee (co-chaired by Tung Nguyen and Joe Guydish) will meet to review the study, and decide if it is ready to be moved forward to the PRC. Site Committees are open, and are a good place for the group to discuss trials and help each other build the best possible trial. Once approved, Kaya will submit the study to the PRC, and then a similar PRC review process takes place.

Q: Does the site committee do more than scientific review of studies?

A: Yes. Since site committee meetings are open, they serve vital functions for discussion of concepts, thinking about research directions for the program, identification of clinical research gaps, etc. Equally important, they are critically important venues for trainees and junior faculty to get group input, and gain from the collective wisdom of the group and more established investigators as they develop their own concepts and trials. The UCSF HDFCCC provides statistical input for clinical trials being developed by new investigators or trainees, and the site committee is a good place to obtain that input.

Site Committees are also expected to monitor accruals to interventional studies, and to help develop corrective action plans if accrual is going much slower than expected. Site committees serve as an important point of contact with the UCSF HDFCCC Data and Safety Monitoring Committee (DSMC). The oversight of DSMC over interventional trials is an NCI requirement.

Q: Who do I contact if I have questions about the process?

A: Kaya Balke, the site committee administrative lead is a great resource for administrative or operational questions. The Site Committee co-chairs, Tung Nguyen and Joe Guydish are also available. Cancer Center leads for units that interact with the site committees are listed below:

PRMS	Staff: Tanya Kocian	Faculty: Jenny Clarke
Clinical Research Support Office	Staff: Andrea Skafel	Faculty: Babis Andreadis
DSMC	Staff: John McAdams	Faculty: Katie Kelley