

## Disease Site Committee Checklist December 17, 2015

- The Chair appoints a Co-Chair with full signatory authority in the Chair's absence or in case of conflict (consideration should be given to appointment of a Co-Chair from a different disease site than the Chair to encourage cross-disease collaboration). Wherever the Chair is the PI on a study, the Co-Chair should conduct all study-related committee business. Likewise, if the Chair is unavailable and the Co-Chair is the PI, review must be delayed until the Chair becomes available, as the Chair must conduct all study-related committee business in such a case.
  
- The Chair ensures that committee membership consists of (at minimum) four relevant clinical investigators, a research nurse or Clinical Research Coordinator (CRC), a statistician (appointed by the Biostatistics Core leadership; ideally with expertise in the relevant disease), and a relevant laboratory investigator. One patient advocate is strongly recommended. Provide the membership roster to the PRC.
  
- Meet at least monthly. Quorum is 50% of the Core membership roster.
  
- Maintain written **minutes** of all meetings, including attendance and decisions concerning accrual, priorities, safety, new concepts, and protocol review. I.e., all reviews using standardized forms, all review outcome correspondence (e.g., Chair or Co-Chair Summary of Review form), and attendance records for each meeting will be maintained in a centralized location (for 2016 forward, on the site committee server; for 2015 and older, in binders), and available for review. Additional written minutes should be prepared to document any committee activity not covered by existing forms. Please keep all minutes for the year in the same location; the Cancer Center may need to access the minutes at a moment's notice for NCI review.
  
- Track all new protocols, concept sheets/letters of intent, and all protocol amendments which impact the budget or accrual or are otherwise urgent in order of priority on one of two lists: one for trials requiring moderate to significant ITR or programmatic resources for activation, and a second for trials requiring few to no resources for activation (e.g., CIRB trials). The committee must determine the order of priority at each meeting. Rank trials using whole numbers, and arrange the list with lowest ranking number at top, highest at bottom.
  
- Prioritize all competing open and proposed protocols for each targeted patient population on a separate list – include trials from outside your program where applicable. A description of how competing trials will be prioritized, or a statement explaining why there are no competing trials, is also required.

- Review all **new protocols** prior to PRC review, and all **new concepts** prior to protocol development; the committee must ensure the concept is developed into proper protocol format and resubmitted for new protocol review:

Ahead of Meeting:

- Chair or designee assigns reviewers (primary, secondary and statistician for some industry and investigator-initiated trials; *single reviewer for cooperative group trials and other Expedited reviews*). PIs cannot be assigned as reviewers, and must attend the meeting. Primary and Expedited reviewers must be faculty and recorded on the member roster. CRCs and RNs may serve as secondary reviewers at the Chair's discretion, provided they're on the roster. Statistical reviewers must be statisticians, but do not need to be recorded on the member roster.
- Reviewers read through the protocol and supporting documents (e.g., survey tools, investigator's brochure, consent form) and complete role-specific review forms (Primary Reviewer's Comments form for primary reviewer, Secondary Reviewer's Comments form for secondary reviewer, Statistical Reviewer's Comments form for statistician, and *Expedited Reviewer's Comments form for the single reviewer assigned to expedited reviews*). Protocols should meet minimum guidelines and standards (see HDFCCC treatment protocol templates at <http://cancer.ucsf.edu/research/cores/crso#inst-trials>)

At the Meeting:

- Quorum is confirmed.
- The primary reviewer presents the protocol (expedited reviewer may do the same if the Chair wishes to hold a committee discussion), and all reviewers discuss their findings. PI or designee must attend the discussion to answer questions.
- All assigned reviewers individually assign an Overall Score.
- The Chair or Co-Chair completes the Chair or Co-Chair Summary of Review form for each protocol reviewed.
  - Record the study phase and type of UCSF involvement.
  - Set the annual target accrual goal and total accrual goal, and record goal justifications.
  - Identify competing trials and perform a feasibility assessment.
  - Calculate the average of all reviewers' Overall Scores to determine the Final Overall Score.
  - Capture final study disposition by collecting the committee's assessment and recording it on the form:

Approval: applicable if there are no changes that must be made to the protocol before it can be initiated

Contingent Approval: requires itemization of concerns that must be addressed before full approval can be granted

Disapproved: requires itemization of concerns that must be addressed before full approval can be granted (requires full committee review of the PI's response).

- Completed review forms are turned in.
- The committee must prioritize all new protocols, concept sheets/letters of intent, and all protocol amendments which impact the budget or accrual or are otherwise urgent on one list.
- The committee must identify all competing open and proposed protocols *for each targeted patient population*, and show how competing trials will be prioritized on a second list. Where applicable, the list should include trials from outside your program provided those trials compete with the applicable patient population.
- Determine if any accrual waivers are to be requested on new studies.
- Concepts are to be discussed and prioritized, but not assigned specific reviewers. The Chair or Co-Chair records the approval status on the Concept Review Form.

After the Meeting:

- Minutes are finalized and review outcomes (Chair or Co-Chair Summary of Review form) distributed to PI and/or designee.
- Add newly reviewed protocols and concepts to the quarterly report.
- Responses to Disapproved studies are put on next available agenda and reviewed as new protocols. The Chair or designee assigns responses to as many original reviewers as possible.
- Responses to Contingent Approval are submitted by applicants using the Contingent Response Review form; *the concerns requiring a response listed on the preceding Chair or Co-Chair Summary of Review Form should be identical to those listed on the Contingent Response Review Form*. The form and any accompanying documents are distributed to original reviewers wherever possible (if a second response to contingencies, the response goes to the Chair or Co-Chair). Original reviewers ensure that all concerns are adequately addressed and the protocol is modified appropriately, and communicate their findings to the Chair or designee. The Chair or Co-Chair adjudicates any reviewer conflicts. When all reviews are in, the Chair completes the Contingent Response Review form turned in by the applicant.
- Approved concepts: provide the HDFCC protocol template to the applicant and request that the concept be developed into full protocol format and brought back to the committee for additional protocol review prior to PRC submission.

- Submit approved protocols to PRC with *all review forms* pertaining to each study: all individual review forms, Chair or Co-Chair summary of review forms, and contingent response review forms.
  
- Review **all protocol amendments** (including administrative revisions) prior to PRC review.
  - At minimum amendments should be approved by the Chair, or designee; discussion by the entire committee or specific reviewers is at the Chair's discretion.
  - PRC Amendment Submission Application Form must be signed by the site committee Chair (or Co-Chair where the Chair is the PI).
  - Submit reviewed protocol amendments to PRC per the PRC Amendment Submission Policy.
  
- Review **safety** at least weekly for Phase I or otherwise high-risk (see definitions in PRMS Disease Site Committee Review Policy) or early phase clinical trials; all other trials reviewed at least monthly. For studies initially reviewed by any Disease Site Committee serving interventional trials crossing many cancer sites, AE review must be conducted by the originating program, *not* the Disease Site Committee which conducted the initial review.
  - Cooperative Group trials: review all ADEERS reports and patient status log prepared by PI or designee.
  - All other Phase I trials: PI or designee will review all grades of adverse events (AEs) and serious adverse events (SAEs) prior to the meeting. This list of all AEs/SAEs along with patient status and cohort accrual (if applicable) will be presented at the meeting and the minutes will reflect the committee review.
  - All other trials (i.e., non-Cooperative Group and non-Phase I trials): review only AEs of Grades 3-5 and patient status log prepared by PI or designee.
  - The summary of AEs for all trials will be signed by the committee Chair or designee and incorporated into the minutes.
  
- Review all enrolling studies (all clinical and non-therapeutic disease- or committee-specific studies) for **accrual** progress at least annually.
  - If accrual is less than projected, evaluate potential reasons for low accrual, formulate a corrective action plan, and document in the minutes.
  - If a clinical trial has accrued less than the minimums in Table 1 – Required Minimum Annual Accrual (see PRMS Disease Site Committee Review Policy) after one year of enrollment, either close the study to accrual or formulate a corrective action plan.
  - Reassess accrual six months following implementation of any corrective action plan. If accrual is not meeting minimum requirements, close the study to further accrual, or terminate altogether.