RRC evaluates all cancer research protocols, including studies of existing (banked) tissue and blood specimens. This internal peer-review process considers the scientific merit, priority, study design, feasibility, and statistical analysis of each proposal (https://www.protonet.fccc.edu/fccc/pims/rrc). This level of review is justified based on the utilization of valuable and potentially limited clinical resources, as well as the adoption of federal regulations that govern patient confidentiality, specimen ownership, and rights to certain information. Following RRC approval, all studies are then evaluated by IRB for determination of appropriate status (full board review, expedited review, or exempt).

In comparison with clinical treatment protocols, it is generally expected that protocols for analysis of existing tissue specimens will be shorter and more limited in scope. For example, a perfectly adequate proposal might only require three pages. However, there are specific components that are essential to the scientific peer-review process.

The following key elements are required for RRC approval:


2. Each study should begin with a title page that includes contact information for all investigators, version number, version date, and a running date list of amendments. Projects that are part of an approved or submitted external peer-reviewed grant application can be submitted with a cover letter and a copy of relevant sections from the grant, provided that the stated criteria are met. Although not required, RRC encourages investigators to submit proposals for internal review prior to grant funding, if appropriate. Award of funding, in and of itself, does not constitute approval of the research project.

3. The study should provide a scientific rationale including literature citations, when available. In general, the study should include at least one scientific hypothesis to serve as a primary study objective. This objective will be used to determine the sample size. Secondary and/or exploratory objectives can also be included, but these will not generally have an impact on the sample size calculation.

4. Studies without a primary hypothesis will be considered as “pilot feasibility studies”, and the number of samples will be limited accordingly.

5. A brief description of the study design should be provided (i.e., what will be done with the samples). This should include a description of the laboratory studies that will be performed. The investigator should provide explicit criteria for what would constitute “success” or “failure” for each objective. In the case of a larger study using more established techniques, a detailed description of those techniques should be provided together with the performance characteristics of the assay(s).
6. The investigator should provide a description of the methodology for quantitating results. A clearly worded description should also be provided of any comparisons that will be performed (e.g., test samples vs historical controls; test samples of abnormal tissues vs normal; results of samples at different stages of tumor progression; etc.).

7. In order to judge the feasibility of the study, the investigators should indicate the degree of difficulty anticipated in acquiring adequate samples (size and number). In the case of existing tissue samples, the study should include realistic estimates of the overall number of available samples for each tissue type. In addition, the amount of tissue requested from each sample should be realistic and appropriate based on the amount stored and nature of the proposed assays. Written confirmation of specimen availability from the appropriate tissue bank is strongly recommended to facilitate review.

8. Each protocol should include a biostatistics section that provides justification for the proposed sample size, as well as power and precision of the primary study analysis. In the case of a small pilot feasibility study in which qualitative descriptions of test results are anticipated, an abbreviated biostatistics section would be sufficient.

9. Anonymized (de-identified) samples and database records are generally used in these studies. Procedures for anonymization and maintenance of patient confidentiality, including secure storage of data, should be described.

10. When appropriate, studies should avoid the introduction of gender and ethnic bias and efforts to this end should be outlined in brief. In addition, if there will be sufficient power to detect potential differences in outcomes related to race and/or gender, this should be explained.

Procedure Notes:

- Following RRC approval, studies may then be submitted to the Institutional Review Board (IRB).
- Following IRB approval, studies may be activated, subject to any additional administrative and/or regulatory review.
- All systematic amendments to the RRC-IRB approved study design should be submitted in a timely manner using standard procedures.
- Ongoing review of all active studies is required by RRC and IRB within 364 days of the most recent approval date. Studies not reviewed within this period of time will be suspended. Please see the IRB web site (https://www.protonet.fccc.edu/fccc/pims/irb) for specific details regarding the process for ongoing review.

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