EXAMPLES OF GRANT APPLICATION WEAKNESSES

MINOR WEAKNESSES

- Suboptimal analysis plan
- Minor mistake/issue in power statement
- Plan seems to make unrealistic demands of patients/clinicians.
- Some experimental details are lacking
- Strategy may be hard to generalize to large populations due to expense or technical requirements.
- Concept is of limited novelty, does not appear to be unique.
- Team is not experienced with the methods proposed.
- Correlate studies for clinical trial lack detail or justification.
- Role of the investigators is poorly described.
- Team has not worked together previously.
- When asked how they will engage advocates, the applicant discusses recruitment or being available to talk with trial participants.
    - A stronger application would talk about advocate organizations they have been involved in their work and/or actual suggestions from advocates for a change in trial design to make the study more patient-friendly.

MODERATE WEAKNESSES

- Missing an analysis plan for an aim or aims
- Incorrect or incomplete power statement
- Inappropriate analyses plan
- When asked to provide significance and impact the applicant quotes the number of patients who have a particular type of cancer and how many die of their disease not how the applicant's approach will lessen the number who die and/or improve the quality of life for cancer patients living with this type of cancer.

MAJOR WEAKNESSES

- The applicant did not read the grant directions carefully or chose not to follow them therefore left required items unaddressed.
- No sample size justification (includes justification for number of animals in in vivo experiments). This requires a power statement for the primary objective/endpoint.
- Incorrect study design
- Project is not feasible.
    - Not feasible due to inadequate length of follow-up to ensure the required number of events for sufficient power.
    - Samples or patients not available.
    - Patient numbers seen at the applicant’s institution are not sufficient to ensure accrual in the allotted amount of time.
    - Key reagent or commitment from collaborator missing
    - Protocol design would make recruitment impossible. For example, biopsies required but no potential benefit to patients.

EXAMPLES OF GRANT APPLICATION WEAKNESSES

MAJOR WEAKNESSES (continued)

  - Investigators/mentors do not have requisite expertise (for example no pathologist or no interventional radiologist if these skill sets are important).
  - Proposed technology has lack of feasibility. For example, injection of a genetic construct that lacks preliminary feasibility data and may not be expressed.
- Project is not clinically useful (significant).
  - Very similar strategy has already been tried and documented to be ineffective.
  - Strategy is only a minor improvement on currently available data or therapies
  - Strategy has inadequate preliminary data to support efficacy. For example, clinical claims are made based on very limited cell line or animal work or is based on outdated science.
- Research plan is poorly constructed.
  - Inadequate elaboration of details suggesting that the plan is not well thought out. For example, key experiments are not mentioned.
  - Experiments are not presented in a logical manner or scientifically justified
  - For a protocol, key features are not well justified and/or described, such as patient selection or treatment to be administered.