

## Critique Template for Advocates

**Application Number:**

**PI Name:**

**Application Title:**

**For Multicomponent Applications:**

**Project/Core #:**

**Project/Core Title:**

**Project/Core Leader's Name:**

**Submitted By:** (Advocate name and role "Advocate")

**Critique:** Prepare one paragraph about each of the following:

1. **Significance:** Briefly address the potential significance of the proposed activities from a patient advocate's perspective, as well as any particular strengths or weaknesses that you may see in how the investigators will go about doing the proposed activities.
2. **Protection of Human Subjects from Research Risk:** (Rate as Acceptable or Unacceptable).
  - a. Briefly describe how the subjects will be recruited and the origin of any human specimens. What do subjects have to do for the study, and are the proposed treatments reasonable?
  - b. Briefly describe risks to the people participating in the study and the protections from those risks (such as informed consent and protection of confidential data) that are proposed. Are the proposed protection mechanisms adequate?
  - c. Briefly describe, from a patient advocate's perspective, whether the knowledge the study is seeking is important and whether there are benefits to the people involved in the study or others.
3. **Data and Safety Monitoring Plan** (look for and review a DSMP if the application involves clinical trial research). (Rate as Acceptable or Unacceptable). Briefly describe the adequacy of the Data and Safety Monitoring Plan: What is the plan to monitor adverse events? What will the applicant do if adverse events occur? Look for a Data and Safety Monitoring Board if the trial is a phase III clinical trial.
4. **Inclusion of Women Plan:** (Rate as Acceptable or Unacceptable). Briefly describe whether women are included, and if not, whether this is appropriate for the study (e.g., a study of chemotherapy for people with prostate cancer would not include women as they do not get prostate cancer.) If they are to be included, is there an appropriate recruitment plan?
5. **Inclusion of Minorities Plan:** (Rate as Acceptable or Unacceptable). Briefly describe whether minorities are included, and if included, does the study project participation rates? Are the rates consistent with the population served in the study? Is there a recruitment plan to ensure appropriate participation rates? If minorities are not included, why not? Is this appropriate? (e.g., a study focused on development of screening materials for a Hispanic population would not include non-Hispanic minorities, but this would be acceptable.)
6. **Inclusion of Children Plan:** (Rate as Acceptable or Unacceptable). Briefly describe whether children are included, and if so, whether the study addresses the specific needs of children. Is there a recruitment plan to ensure appropriate participation rates? If children are not included, is this appropriate for the study? (e.g., a study of chemotherapy for people with prostate cancer would not include children as the incidence of prostate cancer is very low in children.)

**Preliminary Score:** The entry of a preliminary score (numeric or adjective) is optional for the Internet Assisted Review (IAR) system. Please check with your SRA for preliminary score instructions.