

*This comes from the perspective of a regular member (MacLean) of DDK-B – a study section that reviews K01, K08, K23, K99/R00 for NIDDK.*

## Characteristics that Impress Reviewers

1. Candidate
  - a. Healthy publication record at all stages of training
  - b. Track record of fellowship, small grant, or pilot funding
  - c. Strategic training path, focused career goals
  - d. Ownership and leadership in the writing, with all the t's crossed and l's dotted.
2. Goals/Training Plan
  - a. Good balance of didactic, enrichment, and hands-on skill development
  - b. Training activities that are coordinated with the research activities
  - c. K99/R00 – well defined completion of training by year 2; reasonable transition to independence
  - d. Responsible conduct of research- 5 points are specifically addressed (bulleted)
3. Research Plan
  - a. Well-developed graphic of working model, with a clear indication of what aspects will be tested
  - b. Hypothesis driven, with observations that will be significant regardless of the outcome
  - c. Aims that are independent but thematically integrated
  - d. Well-presented preliminary data from candidate or mentors
4. Mentors
  - a. Mentor(s) and mentoring team that appears strategically picked for their expertise or contribution to the training experience
  - b. Solid Funding, track record of success in research and mentorship
  - c. Enthusiastic mentor statements that confirm what is in the proposal; a clear dedication to the candidate's success and independence
  - d. Clear distinction between mentor's program and candidate's independent research
5. Environment
  - a. Enthusiastic support and a pre-existing investment/dedication to the candidate's success (protected time, promotion to faculty, space, etc...)
  - b. A detailed plan outlining the plans for promotion, advancement, and tenure track opportunities; ideally having the candidate be in a tenure-track assistant professor position by the time they submit their first R01.
  - c. Abundant core facilities, enrichment opportunities, and opportunities for collaboration

## Common Weakness with K Awards

1. Candidate
  - a. Modest publication record, with numerous publications in preparation
  - b. A wandering, unfocused training path.
  - c. Lack of enthusiasm in the writing
2. Goals/Training Plan
  - a. Plan is not specific to the candidate- could be for anyone
  - b. Training activities are not integrated well with the research plan
  - c. K99/R00 – training plan extending into the R00 phase of the award
  - d. Responsible conduct of research is not adequately described
  - e. No timeline
3. Research Plan
  - a. Lack of a working model
  - b. Not hypothesis driven
  - c. Not considering limitations/alternatives

- d. No timeline or milestones for success
- 4. Mentors
  - a. Lack of a mentoring team
  - b. Modest funding support or training experience on the team
  - c. Contribution of each member is not clear or strategic
  - d. Mentor statements that conflict with or not well integrated with proposal
- 5. Environment
  - a. Lack of commitment to the candidate's success
  - b. Lack of a reasonable path to independence and R01 funding

## Additional Guidelines from NIH about RCR

Excerpt from: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>

1. **Format:** Substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. **While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.**
2. **Subject Matter:** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:
  - a. conflict of interest – personal, professional, and financial
  - b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
  - c. mentor/mentee responsibilities and relationships
  - d. collaborative research including collaborations with industry
  - e. peer review
  - f. data acquisition and laboratory tools; management, sharing and ownership
  - g. research misconduct and policies for handling misconduct
  - h. responsible authorship and publication
  - i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all of the above topics.

3. **Faculty Participation:** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.
4. **Duration of Instruction:** Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.
5. **Frequency of Instruction:** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual fellows/scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Senior fellows and career award recipients (including F33, K02, K05, and K24 awardees) may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the trainee, fellow or career award recipient is not actually supported by an NIH grant. This instruction can be documented as described below.