

## **GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON MENTORED SCIENTIST DEVELOPMENT AWARD IN RESEARCH ETHICS APPLICATIONS (K01)**

PA NUMBER: PA-99-050

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-99-050.html>

The Mentored Scientist Development Award (MSDA) in Research Ethics supports training in research ethics for health professionals working at academic and other health-related institutions in biomedical, behavioral, or public health research, particularly research involving human participants.

The goals of the MSDA in Research Ethics are two fold: 1) The award should enhance the career of the candidate such that he or she would become an independent investigator in applied research ethics; and 2) The candidate would become a resource in the area of research ethics for the sponsoring institution and its scientific community. As such, applications for the MSDA in Research Ethics should include a mentored research experience that will measurably enhance the candidate's scientific career as a research ethicist.

The MSDA in Research Ethics program is intended to support two kinds of individuals: (1) Those who have an established career in another field (such as clinical medicine, nursing, biomedical or behavioral research, or have a background in the humanities), and now want to move into research ethics; and (2) Those who are already in the field of research ethics but, because of their junior status, require a period of mentored career development in order to become independent scientists in the field of research ethics.

### **CRITIQUE**

Each major review element within the MSDA In Research Ethics application (Candidate, Career Development Plan, Research Plan, Mentor, Institutional Environment and Commitment and Budget/Other Criteria) should be commented on in a separate section of your written critique. For revised applications, also comment briefly on whether the application is improved, the same, or worse. In addition, provide a one-sentence summary of your evaluation at the end of each section. After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit in a section titled Summary and Recommendations (see below). Please note that your comments will be used essentially unedited in the final summary statement sent to the candidate.

The following review criteria should be considered when writing your critique:

#### **Candidate**

- Is the candidate appropriately trained and suited to the proposed career development activities (i.e., well trained and productive in his or her current field and prepared for the proposed career development activities)?

## **Career Development Plan**

- Is the career development plan proposed one which will give the candidate sufficient grounding in principles, content, and methods of research ethics such that the candidate can establish an independent research career in the field?

## **Research Plan**

All candidates for this award will have had previous research experience and in some cases will have been principal investigators in other scientific fields. A sound research plan that is consistent with the career development plan and the candidate's level of research development must be provided.

- **Significance:** Does this project address an important problem? How well does the proposed research experience complement the proposed career development activities?
- **Approach:** Are the methods adequately developed, well integrated, and appropriate to the research plan and career development goals of the candidate? Does the candidate acknowledge potential problem areas and consider alternative tactics?

## **Mentor**

Is the mentor sufficiently qualified, experienced, and available to assist the candidate sufficiently in the proposed career development and research activities?

## **Institutional Environment and Commitment**

- Is the institution's (or institutions' - if the trainee and mentor are located at different institutions) commitment sufficient to increase the probability of success? Is there appropriate collaboration among departments and units within the institution? Are there unique features in the institutional environment that can increase the chances of success? Are the resources adequate?
- Is the applicant institution willing to develop an appropriate mix of research, teaching, and administrative responsibilities for the candidate?

## **Budget/Other Criteria**

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following criteria where they are applicable:

- Plans for the recruitment and retention of human participants
- The reasonableness of the proposed budget and duration in relation to the proposed activities

- The adequacy of the proposed protection for humans, animals, or the environment to the extent they may be adversely affected by the activities proposed in the application.

## **SUMMARY AND RECOMMENDATION**

In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the six review criteria. An application does not need to be strong in all categories to receive a good rating. Each scored application will receive a numerical rating that will reflect your opinion of its merit. The numerical rating is based on a scale from 1.0 for the most meritorious to 5.0 for the least meritorious with increments of 0.1 unit. Reviewers should score the "average" application they customarily review in their Scientific Review Group with a score of 3.0. This practice is designed to have 3.0 be the median.

## **OTHER CONSIDERATIONS**

**Foreign Training:** In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

**Protection Of Human Subjects From Research Risks:** Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

**Gender, Minority And Children Subjects:** Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If

the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender Unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

**NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under the "Research Plan" section of the critique, and should be factored into the score as appropriate.**

**Animal Welfare:** Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

**Biohazards:** Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

*Further information about NIH research training and career development opportunities can be found at <http://grants.nih.gov/training>*