

**Questions from the U54 Application Briefing**  
**Tuesday, February 19, 2002**

- **Why is there so much variability occurring?** Genetic and epigenetic events may account for individual variability and thus is a primary focus of the RFA. We need to look beyond observational studies to determine who will and will not benefit from intervention strategies.
- **Question: Do you have to limit yourself to one gene?** Applicants can concentrate on one gene with multiple nutrients or focus on multiple genes influenced by one nutrient. We are seeking the strongest application and thus providing investigators with considerable flexibility.
- **Question: Will the successful U54 cover all (3) items just mentioned (genes in the environment, molecular targets and cell signatures)?** No, you can pick one of them or multiple ones if you want, but probably just one.
- **Question: Does there have to be an Epidemiological study incorporated in the application?** The application has to be based on compelling evidence that a nutrient influences a genetic pathway leading to cancer. This can come from a variety of sources including pre-clinical, epidemiological, or clinical investigations. An epidemiological study will likely not be part of these applications unless small in scope because of the funds available (about \$1.75M per year per award).
- **Question: Please clarify institutional equipment?** Anything that an applicant can provide which reveals the support of the institution(s) involved. A monetary commitment is not required but availability to facilities and overall infrastructure is important to documenting that the proposed studies can be completed in a timely manner.
- **Question: If we already have established collaboration, should we play this up at NCI?** Yes, always document the strengths of those involved including those within NCI. If there are resources that are required, please request and we will do our best to assist.

**Please contact John A. Milner with additional questions and concerns:**

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1. Must there be at least one pilot project in the application?

**Yes, the RFA states that every team must facilitate and support Pilot Projects.**

“...Every Team must facilitate and support Pilot Projects that take maximum advantage of new technological and research opportunities... If a clinical trial is not proposed as one of the Research Projects, at least one Pilot Project must outline the general plan for a (future) clinical trial that incorporates the methodologies, techniques, and probes to be developed in the research projects. Each application must propose an institutional review process for selecting Pilot Projects for funding that generate feasibility data and have the most promising translational research potential...”

2. Will the application be accepted if investigators already have applications pending for review, or reviewed that overlap with the proposed U54 application? (This concerns the following statement from the RFA: “The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed.”)

**For purposes of this RFA, exception #2 below (from the PHS 398 application, 5/01 rev.) applies to individuals submitting an individual research project identical to a subproject that is part of the U54 application.**

“Submissions of identical applications to different agencies within the PHS or to different Institutes within an agency are not allowed. Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially

identical research in an application for an individual research project; and 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.”

3. Regarding acknowledgement of Federal support, **please refer to the NIH Grants Policy Statement (03/01), Part I: NIH Grants-General Information--Part 1 of 2.**

“...The PI...works closely with designated officials within the grantee organization to...ensure that Federal support of research findings is appropriately acknowledged in publications, announcements, news programs, etc. (see "Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources"); and comply with organizational as well as Federal requirements...”

4. Does “institutional commitment” include matching or cost sharing? This concerns the following statements from the RFA: “...All research approaches are encouraged, as long as they address the following essential features: a cancer focus, institutional commitment, organizational capabilities, facilities, and interdisciplinary coordination and collaboration...” “ In addition, the criteria for reviewing the integrated effort are: Demonstrated institutional commitment to the investigators and their objectives in terms of providing research facilities and management support...”

**There are no specific “cash” matching or cost sharing requirements under this RFA. Institutional commitment in this context means research facilities, management support, etc.**

5. May subproject PIs be non-US nationals?

**The RFA states that PIs must be United States citizens, non-citizen alien nationals, or permanent residents of the United States. This requirement does not apply to foreign subprojects/components.**

**Please contact Priscilla Grant for additional questions or concerns regarding the U54 briefing.**

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