Partnerships for Hepatitis C Vaccine Development (RFA-AI-05-030)

The purpose of this request for applications (RFA) is to stimulate the development of vaccines against infection with Hepatitis C Virus (HCV) and its chronic sequelae. Research may include but is not limited to one or more of the following: 1) the design and construction of vaccines against HCV infection; 2) preclinical evaluation of vaccine candidates; and 3) pilot scale manufacture of vaccine candidates.

A key component of this initiative is the development of appropriate partnerships between the government and industry. For the purpose of this RFA, "industry" is defined as large and small, domestic or foreign, pharmaceutical, biotechnology, bioengineering, and chemical companies. Since academic organizations are often the source of new discoveries and leads for candidate products, this RFA can also support a partnership between industry and a collaborator(s) as necessary from academic or non-profit research organizations. The involvement of an academic or non-profit research organization is NOT a requirement; therefore, industry does not need a collaborator to submit an application to this program.

All projects must demonstrate substantive involvement by the industry partner. For the purpose of this RFA, "substantive involvement" is defined as the commitment of any one or more of the following resources: funds; personnel; or in-kind contributions of materials and/or reagents including, but not limited to, recombinant protein production, provision of animal or other laboratory models, and assays, subcontracts, data management resources or regulatory support. The Principal Investigator of the project may be affiliated with either industry or academic organizations (if academia is part of a partnership with industry). This funding opportunity will use the U01 award mechanism.

The full text of the RFA may be found at: (http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-05-030.html).

Cooperative Agreement Terms and Conditions of Award

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement (U01 single-project), an "assistance" mechanism (rather than an "acquisition"

mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined above.

Principal Investigator Rights and Responsibilities

The Principal Investigator will have the primary responsibility for: setting forth the research plan, defining the aims and objectives, describing the methods, techniques and other resources to be used, and for carrying out the described work.

Intellectual Property

The successful development of products for infectious diseases, including Hepatitis C, will require substantial investment and support of private sector industries and may also involve collaborations with multiple organizations, including academic and/or non-profit research institutions. It is the intent of this initiative to support the formation of the appropriate public-private partnerships that are essential to meet these critical public health needs. NIAID recognizes that intellectual property rights are likely to play an important role in achieving the goals of this program. To this end, all awardees understand and acknowledge the following:

- The awardee is solely responsible for the timely acquisition of all appropriate proprietary rights, including intellectual property rights, and all materials needed for applicant to perform the project;
- Before, during, and subsequent to the award, the U.S. Government is not required to obtain for awardee any proprietary rights, including intellectual property rights, or any materials needed by awardee to perform the project;
- Awardee is required to report to the U.S. Government all inventions made in the performance of the project, as specified at 35 U.S.C. Sect. 202 (Bayh-Dole Act).

Awardees are expected to make new information and materials known to the research community in a timely manner through publications, web announcements, and reports to the NIAID or other mechanisms.

Annual Progress Review Meetings

The Principal Investigator and one or two key personnel designated by the Principal Investigator of each grant awarded under this RFA shall participate, with NIAID Program staff and any external advisors (when applicable), in annual meetings to review progress and aid in program development. These annual meetings shall be held at the NIAID offices in Bethesda, Maryland, at one of the awardee institutions, at a scientific meeting,

or at another site determined by NIAID Program staff. Additional meetings, which may be necessary for coordination of cooperative agreement activities, may be scheduled.

Publications

The Principal Investigator will be responsible for the timely submission of all abstracts, manuscripts and reviews (co)authored by members of the grant and supported in part or in total under this Cooperative Agreement. Manuscripts shall be submitted to the NIAID Program Officer within two weeks of acceptance for publication. Publications or oral presentations of work performed under this Cooperative Agreement will require appropriate acknowledgement of NIAID support. Timely publication of major findings is encouraged.

Data

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

NIH Responsibilities

An NIH Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below.

During performance of the award, the NIH Project Scientist, with assistance from other scientific program staff who are designated based on the research topic and their relevant expertise, may provide appropriate assistance, advice, and guidance by: participating in the design of the activities; advising in the selection of sources or resources; advising in project management and technical performance. However, the role of the NIH Project Scientist will be to facilitate and not to direct the activities. It is anticipated that decisions in all activities will be reached by consensus between the Principal Investigator and the NIH Project Scientist, and that NIAID staff will be given the opportunity to offer input into this process. The NIH Project Scientist will facilitate liaison activity for partnerships, and provide assistance with access to NIAID-supported resources and services.

Additionally, the NIH Project Scientist will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The Government, via the NIAID Program Official, will have access to data generated under this Cooperative Agreement and may periodically review the data and progress reports. NIAID staff may use information obtained from the data for the preparation of internal reports on the activities of the study. However, awardees will retain custody of and have primary rights to all data developed under these awards.

Release of each annual funding increment by NIAID will be based on an NIAID review of progress towards achieving the previously agreed upon research goals, interim

objectives and milestones. The NIAID reserves the right to terminate or curtail a study (or any individual award) in the event of inadequate progress, poor quality, or other major breach of the approved project.

Collaborative Responsibilities

The specific timelines, interim objectives and funding levels agreed to by the awardee and the NIAID shall be included in the terms and conditions of award. Given the nature of product development, it is recognized that timelines and interim objectives may require revision and renegotiation during the course of the project period. The Principal Investigator and NIAID must agree to all such revisions. In order to advance the development of a lead vaccine candidate, NIAID may ask awardees to collaborate or cooperate with other NIAID-funded projects and/or U.S. government agencies, for example, CDC, FDA, and/or USDA.

External Advisors

External advisors may be appointed by the Principal Investigator in consultation with NIH Project Scientist to assist in progress review. External advisors will be identified and appointed only after award.

Arbitration Process

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and HHS regulations 45 CFR Part 16.