CHNR PILOT RESEARCH GRANT FULL APPLICATION

CHNR Objective: To support research projects that propose innovative, 21st century biology based approaches to the investigation of how nutrients, and combinations of nutrients in whole foods, can act to reduce the risk for chronic diseases.

CHNR Award Terms: CHNR Pilot Research Grant awards can be made for up to **two (2) years**. Annual total funds requested **cannot** exceed **$52,500**. Indirect costs are 5% of total direct costs. Allowable expenses include salaries, fringe benefits, supplies, equipment, and domestic travel..

INSTRUCTIONS

When applying:

Read this entire document before you begin!

- **Provide e-mails for PIs and all Institutional Contacts that are user-specific. Do not provide generic e-mails such as: ContractsandGrants@myinstitution.edu**

- **Paginate the "Research Plan" section of your application only. Do not number the other forms.**

Deadline and Submission Policies

- **Due date for return of the full proposals to March 19th at 5PM PDT**
- **Late applications will not be accepted.**
- **Applications from non University of California Davis PI's must be approved by the applicant institution's Contracts and Grants Office or comparable unit.**
- **Submit the full application to CHNR via either**
    - **e-mail: CHNR@ucdavis.edu with the grant package as an attachment**
    - **or by mail: CNHR Pilot Studies, Department of Nutrition, Meyer Hall, University of California Davis, Davis CA 95616.**

EVALUATION

Relevant applications will be evaluated by members of the VSFSC along with if necessary ad hoc reviewers. CHNR evaluation procedures will follow the NIH peer review process, employ a similar rating scale and evaluate the strengths and weaknesses of each Research Project proposal relative to the following criteria:

- **Significance**: Does the study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of theses studies on the concepts or methods that drive this field?

- **Approach:** Are the conceptual framework, design (including composition of study population), methods, and analyses adequately developed, well-integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is the proposed work feasible?

- **Innovation**: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

- **Investigator**: Is the principal investigator and other key personnel listed in the grant proposal appropriately trained and well-suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other researchers (if any)?

- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

- **Research risks:** If a project proposes activities that involve humans or animals, are there potential risks? If so, is there sufficient documentation of the proposed means for protection against harm? Approved institutional assurances do not need to accompany applications but are required prior to release of funds.

- **Impact:** Future plans for follow-up and funding upon completion of grant awarded.

HUMAN AND ANIMAL SUBJECTS ASSURANCES

Before awards are made, CHNR must receive institutional approvals and assurances regarding the treatment of human or animal subjects. Moreover, the CHNR in compliance with the policy of the University of California requires that research involving human subjects include members of ethnically and racially diverse groups and persons of both genders in study populations to fullest extent feasible given the research proposed. If adequate inclusion of one gender and/or diverse populations as subjects is impossible or inappropriate, the rationale must be clearly explained and justified.

DIRECT COSTS

Allowable direct cost expenses may include administrative costs, but only under two conditions:
a) the services, functions, or activities are directly necessary for the conduct of the grant research; and
b) these administrative costs have not been included in the calculation of the recipient institution's indirect cost rate agreement approved by the federal government. Be careful to ensure that any such costs adequately meet both of the above conditions.

DETAILED INSTRUCTIONS

Formatting Guidelines
An application will be considered complete and acceptable for review only if it is legible, in English, follows the specified instructions, and the material presented is sufficient to permit an adequate review. CHNR application templates may be duplicated but not changed; altered templates will not be accepted.

- **Text must have the following specifications:**
  - Font: Times New Roman or Arial
  - Size: No less than 11 pts and for figures and graphics and no less than 9 pts for legends
  - Spacing: Normal
  - Line spacing: Single
  - Density: Must be no more than 15 characters and 6 lines per inch
  - All four margins must be at least half an inch, except for pre-formatted CHNR templates.

- **The Principal Investigator's name (last name, first name, and middle initial) must be in the designated space located in the upper right-hand corner of each form of the application.**
- **Applicant must not exceed page limits for each section of the application. The Research Plans will be screened to identify those that violate the formatting criteria (number of pages, font size, text density, and margins). If there is any violation, the PI will be notified that the proposal will not be submitted for peer review and is ineligible for funding in that cycle.**
- **Appendices must be limited to material pertinent to the review process and may not be used to circumvent the page limit for the Research Plan.**

Face Page

Lay Abstract (One page)
Describe using layman's language, background, the question being asked, its importance, the approach to be used and the effects if the aims are achieved.

Scientific Abstract (One page)
Detail succinctly previous work/state of the science, research hypothesis, the approach(es) to be used to address it and the results expected, the limitations and future plans if the aims are achieved.

Key Personnel
List all individuals, including consultants/collaborators, who will have significant intellectual input into the scientific development and execution of the proposal, regardless of whether they will draw a salary from this project. For every individual, include advanced degrees position title, department and institution, as well as role in project.

Biosketch
Attach a Biographical Sketch for the PI and each person listed in the Key Personnel section. Limit each Biographical Sketch to three (3) pages and PHS forms and NIH Biosketches are acceptable.

Other Support
"Other Support" is defined as all funds or resources, whether federal, non-federal, or institutional, available to the PI named in the application in direct support of their research endeavors through research or training grants, cooperative agreements, contracts, and fellowships. The "Other Support" form must be completed and must document all currently funded and pending participation (regardless of whether salaried or not) in other organized research projects for the **PI only**. Information on other support should be provided on the "Other Support" template and continuing on additional pages if necessary. Principal Investigator's name should be on the upper right hand corner of each page. If the PI has no other support, write "NONE" under the individual's name on the form. Follow the NIH Guidelines

(http://grants.nih.gov/grants/policy/person_months_faqs.htm) and Calculation scheme (http://grants.nih.gov/grants/policy/person_months_conversion_chart.xls) for showing Months Devoted to Project: For those projects identified as overlapping or are in any way relevant to the CHNR application, Specific Aims must be provided. **NOTE:** Revised "Other Support" pages must be submitted prior to release of funding for awards.

DETAILED BUDGET/JUSTIFICATION
Provide a detailed budget page for each year of the proposed project. CHNR limits the inflation factor to 5% per year.

Personnel
List by name and job title all personnel who will participate in the project, if known; if not known, use the position titles. For each person, enter in:

Column 1: the percent FTE (full time equivalent) appointment at the applicant institution;
Column 2: the FTE percent time devoted to this project;
Column 3: the FTE percent salary requested (which cannot exceed the percent time devoted to this project).

When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income (e.g., clinical or consulting incomes). Graduate students may be paid as personnel on CHNR awards and may also receive tuition remission.

Consultant and Contractual Costs
Enter the name(s) and role(s), and the total annual costs for each consultant and/or consortium/contractual organization.

Supplies and Expenses
Itemize supplies and expenses in separate categories (such as glassware, chemicals, radioisotopes, publication costs, computer charges, rental agreements, etc.).

Equipment
List each item of equipment over $5,000 separately. Research projects have no specified monetary limit on equipment purchases.

Travel
CHNR requires that travel expenses be divided into 2 categories: Please follow the rules below in preparing the budget for each travel category:
1) Project-Related Travel: Project-related travel must be fully explained in the budget justification. Expenses in this category must be related to completion of the project, such as travel to survey sites to collect data or domestic travel to other institutions to analyze samples or perform experiments, and
2) Scientific Meeting(s): Up to a maximum of $2,000 per year is allowed for domestic travel to scientific meetings.

Budget Justification
Provide a detailed justification of the budget for the first year and subsequent year. Describe the duties of each participant in this project and justify by category all requested expenditures. The budget justification is limited to a maximum of one page (1). CHNR will examine budgets closely and will delete or reduce items not adequately justified.

FACILITIES & RESOURCES

Briefly describe the facilities and resources that are needed and available for successfully

carrying out the proposed research.

Make sure all of the requirements of the proposed research plan are addressed in this section. Justify any reliance on resources external to the institution and provide documentation of their availability to you. Be certain that all subcontractors have the capability to perform the tasks assigned to them.

RESEARCH PLAN

The description of the proposed research may not exceed ten (10) pages, inclusive of figures and references. The Principal Investigator's name (last name, first name, and middle initial) must be printed in the upper right-hand corner of every page. Descriptions of human and vertebrate animal subjects should be detailed on the appropriate forms (see “Human Subjects” and ‘Vertebrate Animals’ templates).

The proposed research project should be described in sufficient detail for peer reviewers to evaluate its research merit. The Research Plan should begin with the listing of Specific Aims. The subsequent text should describe in detail the approach proposed to achieve each of these aims. This elaboration should include all of the following which apply and any other information pertinent to the Research Plan: the problem to be investigated and an explanation of its significance; relationship of the proposed research to previous or ongoing research, including results of any preliminary studies; hypotheses, and rationale for approach to the problem; overall research design, including details of methodology and data analysis; and proposed timetable.

Literature cited in the Research Plan should be listed immediately following the Research Plan and Please **Note: the Page limit for Research Plan includes references.** Citations must include the author(s), title, journal or book title, year of publication, volume, and inclusive page numbers. **Paginate the Research Plan section (1…n).**

HUMAN AND VERTEBRATE ANIMAL SUBJECTS

This form is required for all applications, whether or not the proposed research involves human or vertebrate animal subjects. Check the appropriate response(s).

If your research plan involves the use of human subjects, check the appropriate response and address on this form the following areas in a succinct fashion. Note: when research involving human subjects will take place at collaborating site(s) or other performance site(s), provide the same information for each such institution.

1. Provide a detailed description of the proposed involvement of human subjects in the work outlined in the Research Plan.

2. Describe the sources of research material or the characteristics of the subject population, including its anticipated number, age range, and health status. Applicants must identify the criteria for inclusion or exclusion of any subpopulation whose rationale must be clearly explained and justified. Applications without such documentation are ineligible for funding and will not be evaluated.

Documentation of Assurances for Human Subjects

The applicant and their organization by providing documentation of IRB and or approval will be held as certifying to the CHNR that the research proposal's potential benefits and risks, plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained, who will seek it; the nature of the information to be provided to the prospective subjects; and the method of documenting consent have been provided to and evaluated by the IRB identified as approving the protocol. Please provide this material in the Appendix, if available at the time of submission, include official documentation of approval by the IRBs of all participating institutions, showing the title of this application, the Principal Investigator's name, and the inclusive

approval dates; do not include supporting protocols. Approvals obtained under a different title, investigator, or organization are not acceptable, unless they cross-reference the proposed project. If review is pending, final assurances should be forwarded to CHNR as soon as possible, but no later than July 1, 2007. Funds will not be released until all assurances are received by CHNR.

If your research plan involves the use of animals, the following points must be addressed. When research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this same information.

1. Provide a detailed description of the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

Documentation of Assurances for Vertebrate Animals
The applicant and their organization by providing evidence of animal care committee protocol approval to the CHNR will be held as certifying to the CHNR that all the issues regarding scientifically sound, ethical research using the vertebrate animals selected have been provided to and evaluated by the IUAC identified as approving the protocol. Please provide this material in the Appendix, if available at the time of submission, include official documentation of approval by the IUAC s of all participating institutions, showing the title of this application, the Principal Investigator's name, and the inclusive approval dates; do not include supporting protocols. Grants will not be awarded for research involving vertebrate animals unless the program for animal care and welfare meets the standards of the AAALAC or the institution has a U.S. Public Health Service assurance. If review is pending, final assurances should be forwarded to CHNR as soon as possible, but no later than July 1, 2007. Funds will not be released until all assurances are received by CHNR.

APPENDIX COVER SHEET

- **All applications must include an Appendix Cover Sheet regardless of whether appendix material is included or not.**
- **Appended material is limited to that pertinent to the review process and may not be used to circumvent the page limit for the Research Plan**

Allowable documents:

- Copies of assurances for human subjects and vertebrate animals.
- Subcontract agreements and budgets.
- Miscellaneous letters of support (e.g., letters of collaboration, commitments to provide research resources, letters from consultants, and letters of acknowledgment for UC employees named in non-UC grant applications).

CHNR Policies

CONFIDENTIALITY OF SUBMITTED MATERIALS

CHNRP will maintain the confidentiality of all submitted materials to the fullest extent permissible by applicable law. For funded applications the CHNR will make public: the title, the Principal Investigator, the name of the organization, a lay abstract of funded work, and the total cost

POLICY REGARDING SCIENTIFIC MISCONDUCT

The CHNR as part of the University of California manages its research programs in general accord with the policies and procedures employed by the National Institutes of Health (NIH), including those that apply to scientific misconduct. The Department of Health and Human Services' (HHS) Office of Research Integrity is responsible for implementing HHS regulations regarding scientific misconduct in research conducted with NIH and other support from the US Public Health Service.

The administrative actions imposed by HHS include the following: correction of the scientific literature; special plan of supervision to ensure integrity of the scientific research; certification of the accuracy of the scientific data; certification of the accuracy of sources and contributions for scientific ideas and writings; prohibition against service on PHS advisory committees or as a consultant; and debarment from receipt of Federal funds. These actions are for a specified duration, depending on the nature and seriousness of the misconduct. CHNR follows these guidelines and remedies involving scientific misconduct.

Applicants for or recipients of grants from the CHNR must promptly inform the University of an administrative action or notification of disciplinary action by HHS, either at the time of application or within 30 days of the notification of disciplinary action or imposition of the administrative action. In general, the University will apply the same administrative or disciplinary action. For example, if HHS has debarred an investigator from applying for or receiving NIH awards for a specified period of time, that investigator would also be excluded from applying for or receiving awards from the CHNR.

POLICY REGARDING CONFLICT OF INTEREST

I. Introduction

Stewardship of public funds that support research programs is a public trust and requires that the CHNR take appropriate steps to ensure high quality results. The CHNR therefore requires:

a. institutions ("recipient institutions") that receive research funding from CHNR to establish safeguards to ensure that the design, conduct, and reporting of research funded by CHNR awards will not be, nor appear to be, biased by any significant conflicting financial interest of those investigators responsible for the research.

b. Provide guidance on standards and procedures that recipient institutions are to use in implementing such safeguards.

II. Requirement that Recipient Institutions Have a Conflict of Interest Policy

Each institution receiving CHNR funds must have written, enforced policy guidelines on avoidance of conflict of interest. The institution's policy guidelines should reflect federal, state and local laws and must cover significant financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery. The institution's policy guidelines must indicate how an investigator's outside activities, relationships, and significant financial interests will be reviewed by a responsible institutional official in order to determine whether those activities or interests amount to a conflict of interest in research.

III. Required Disclosure, Review and Management Procedures

a. A recipient institution must require each investigator who is planning to participate in the research proposed for CHNR funding to disclose to an official(s) designated by the institution a listing of his or her

known Significant Financial Interests (and those of his or her spouse or registered domestic partner and dependent children):

i That would reasonably appear to be affected by the research for which CHNR funding is sought; and

ii In entities whose financial interests would reasonably appear to be affected by the research.

b. The designated institutional official(s) must review all financial disclosures and determine whether a conflict of interest exists. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research for which CHNR funding is sought. If the designated official determines that a conflict of interest exists, he or she must determine what actions should be taken by the institution to manage, reduce, or eliminate the conflict of interest.

c. Prior to the expenditure of any funds awarded by CHNR, a recipient institution must report to CHNR the existence of any conflicts of interest found by the institution and provide CHNR with documentation that the institution has acted to protect CHNR-funded research from bias due to the conflict of interest by ensuring that the interest has been effectively managed, reduced, or eliminated.

The following definition of "Significant Financial Interest," adopted by CHNR, is drawn from the federal regulations promulgated by the U.S. Public Health Service (PHS) (42 CFR Part 50 Subpart F 50.603):

> *Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:*
>
> *(1) Salary, royalties, or other remuneration from the applicant institution;*
> *(2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;*
> *(3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities*
> *(4) Income from service on advisory committees or review panels for public or nonprofit entities;*
> *(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or*
> (6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

IV. Applicability

a. This policy applies to all CHNR recipient institutions that also have awards from PHS or NSF and that therefore have conflict of interest policies and procedures in place that comply with those agencies' rules.

b. Recipient institutions that do not have PHS or NSF funds must develop and follow policies and procedures pursuant to this policy. CHNR staff will assist in this process, for example, by providing model language from other institutions or facilitating the cooperation of partner institutions.

c. However, recipient institutions that do not have PHS or NSF funds and believe their investigators have no conflicts of interest related to the research to be funded by CHNR may request a waiver from the requirement to develop written policies and procedures. In order to receive such a waiver, an institutional official must certify in writing that he or she has reviewed the CHNR policy and has determined that no investigator who is planning to participate in the research proposed for CHNR funding has a conflict of interest related to the project to be funded by CHNR.

CONDITIONS OF AWARDS

Awardees are expected to account for the expenditure of grant funds and for the performance of work as agreed upon in a timely manner, so that CHNR may file reports and answer inquiries from VSF oversight personnel and the public. Allowable expenses include salaries and fringe benefits for professional and support personnel, supplies, equipment, and domestic travel costs incurred after the start date of the award. CHNR award funds may be used only for expenditures necessary to carry out the approved research; only domestic travel is permitted. All rights to inventions conceived or reduced to practice during the performance of the award are the property of The Regents and will be disposed of in accordance with the University of California Patent Policy.

Prior to funding, grant awardees must:

- Provide CHNR with a hard copy of the application face page with original signatures
- Provide human and animal subject assurances from federally licensed review board
- Modify titles and lay abstracts, if requested
- Submit revised budgets, if required
- Resolve other administrative issues identified during the review or funding decision process
- **If all assurances, budgetary matters, and administrative matters are not resolved in a timely fashion, the award offer will be withdrawn.**

After funding, grant awardees agree to:

- Use award funds only as approved by CHNR, maintain accounts, records, and other evidence pertaining to work performed and costs incurred
- File annual progress reports and a final scientific report on time
- File annual fiscal reports and a final fiscal report on time
- Communicate with the public about the funded work
- Acknowledge the support of CHNR on all publications resulting from the funded research. This should take the form of " "This work was supported by a grant from UC Davis CHNR which was established with funding from the State of California Vitamin Price Fixing Consumer Settlement fund"