



Office of
Dietary Supplements
National Institutes of Health



NIH Botanical Research Centers Program

Applicant Information Meeting

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National Institutes of Health

U.S. Department of Health and Human Services



Congressional Mandate Botanical Initiative 1999

“Establish a botanical research initiative with major research institutions in the United States”





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NCCAM

**National Center for Complementary
and Alternative Medicine
National Institutes of Health**

What is a Dietary Supplement?

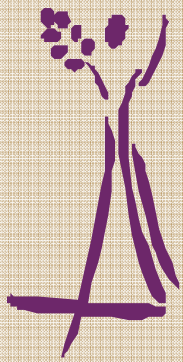


A product (other than tobacco) that

- is intended to supplement the diet
- contains one or more dietary ingredients:
 - vitamins
 - minerals
 - **Herbs or other botanicals**
 - amino acids
 - other substances and their constituents
- **is intended to be taken by mouth**

Intended Use (FDA Regulation)

“Dietary supplements are not intended to diagnose, cure, mitigate, treat, or prevent disease.”



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“ODS has a particular interest in botanicals as part of health care for conditions relating to health maintenance or primary prevention.”



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1. NCCAM shares significant overlap with the interests of ODS
2. Limited emphasis on treatment
3. Advanced technologies for the characterization of botanicals



“NCI Division of Cancer Prevention is interested in supporting research focused on mechanisms by which botanically derived bioactive food components might influence cancer risk and tumor behavior”

What is a Botanical?

- Whole plants or plant parts (e.g., bark, leaves, stems, roots, flowers, fruits, seeds, berries, extracts)
- Medicinal Plants and Foods
- Algae and macroscopic fungi



Ginkgo
Ginkgo biloba



Cranberry

Vaccinium macrocarpon



Flaxseed

Linum usitatissimum



Green Tea

Camellia sinensis

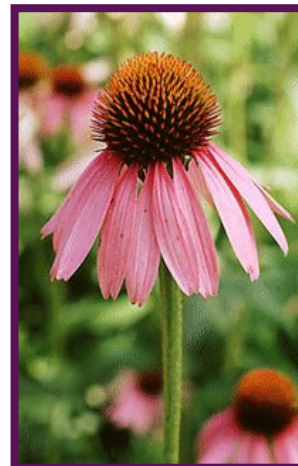


St. John's Wort

Hypericum perforatum

Sample Research Questions

- Does Soy Have Beneficial Skeletal Effects in Postmenopausal Women?
- Can Black Cohosh Alleviate Menopausal Symptoms?
- Does Echinacea Have Antiviral Activity?
- Do Blueberries Improve Insulin Sensitivity?





Botanical Research Centers

- Multidisciplinary Teams
- Emphasis on Quality Assurance/Quality Control
- Emphasis on Basic Science (Mechanisms of Action)
- **Identify Active Constituent(s) and Explore Mechanism(s) of Action**
- Clinical Evaluation (optional)
- Thematic Focus With High Public Health Impact

Botanical Research Centers: Goals RFA 0D-09-001



- Advance the Spectrum of Botanical Research Activities- Ranging From Plant Identification to Early Phase Clinical Studies (optional)
- Characterize Chemical Composition of Botanicals and Study Their Biological Effects

Botanical Research Centers: Goals RFA 0D-09-001



- Cultivate the Use of Contemporary Technologies and Innovative Research Approaches
- Develop and Improve Preclinical Model Systems

Botanical Research Centers: Goals RFA 0D-09-001



- Promote Integrated, Collaborative, Interdisciplinary Study of Botanicals Relevant to Dietary Supplements

P50 Issues



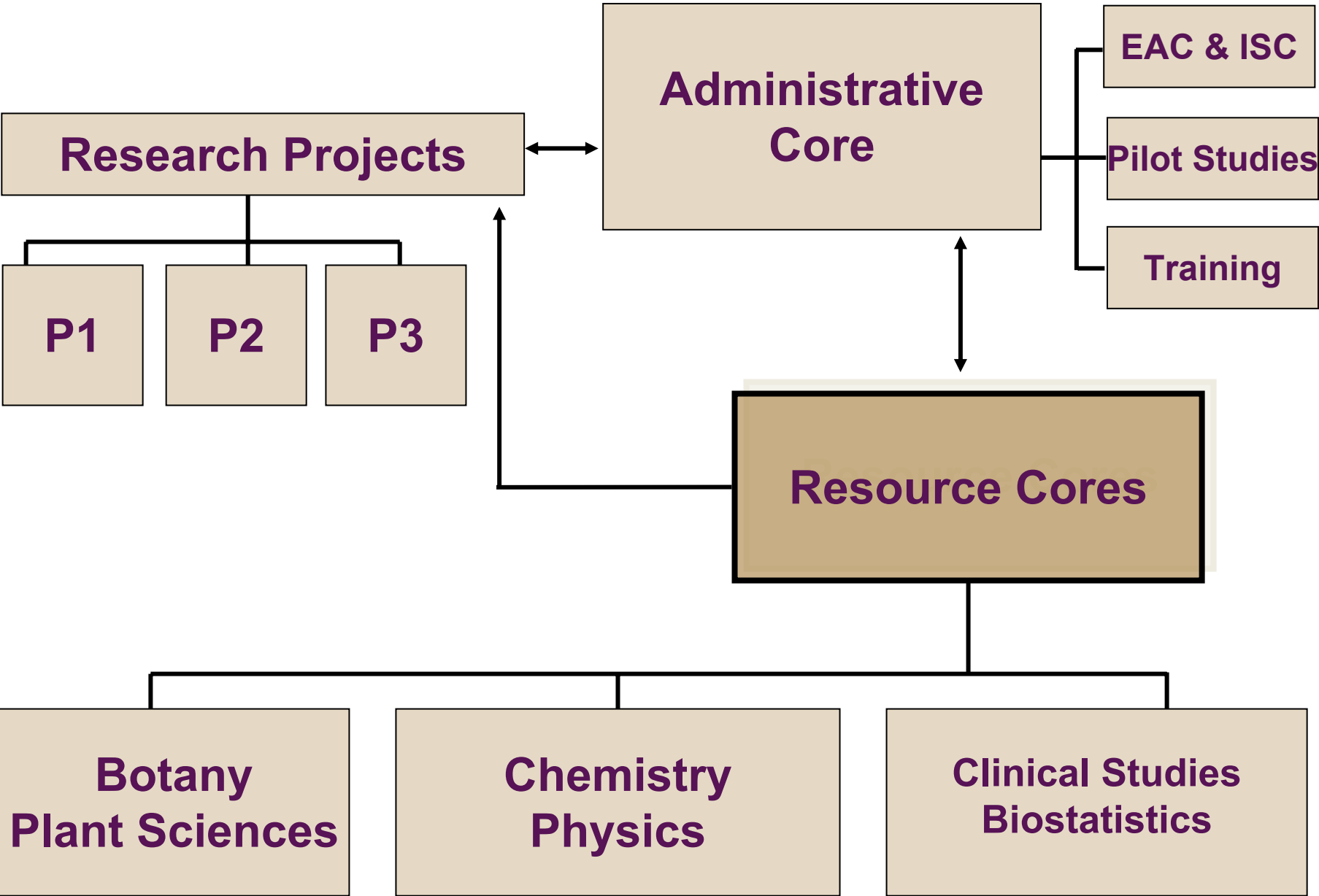
- Research Projects Must be Hypothesis Driven
- Cores to Support Projects
- Whole Must be Greater Than Sum of Parts

P50 Issues

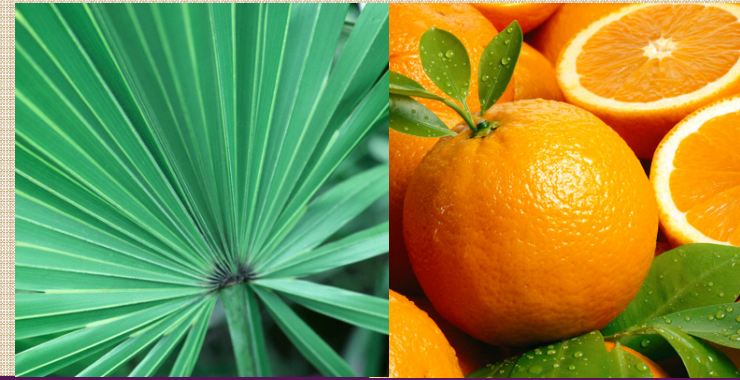


- Complex Research Structure
- Effective Administration Essential
- Qualifications of Center Director (PI)

CENTER STRUCTURE



Thematic Focus



- Requirement of RFA
- Focal Point for Research Activities
- Promotes Synergy
- Relevance to Dietary Supplements

Research Theme (RFA examples)



- The effect of botanicals on a biological process (e.g., inflammation) with multiple clinical endpoints
- Biological effects of botanicals on an organ system (e.g. gastrointestinal, cardiovascular)
- Biological effects of botanicals enriched with a class of bioactive compounds

Research Theme (Additional Considerations)



- Potential for the research to be translated into practical benefits for human health
- Relevance to dietary supplements

Botanical Research Challenges



- Botanicals Expose Consumers to Complex Chemical Mixtures
- Active Constituent/Constituents May Not Be Known
- Constituents Within Botanicals May Have Synergistic or Antagonistic Effects
- Potential for Matrix Effects

Study Materials Must be Adequately Characterized

- Sourcing of Botanical Materials
 - (Herbarium Specimens)
- Processing
- Chemical Characterization
- Quality Control

Biologically Active Agents Used in CAM and Placebo Materials — Policy and Guidance
<http://nccam.nih.gov/research/policies/bioactive.htm>

Botanical Research Opportunities

- Availability of Contemporary Technologies
 - Genomics, Proteomics, Metabolomics
 - Mass Spectrometry
- Collaboration/Team Science





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