PREVENT Cancer Program

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Division of Cancer Prevention
National Cancer Institute
OVERVIEW

NCI DCP-supported pipeline to bring **new high-priority** cancer preventing interventions AND biomarkers through preclinical development towards clinical evaluations.

Current areas of focus:
- Anti-inflammatory approaches
- Immunoprevention
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**WHAT**

- Pipeline focused on unmet needs in prevention that are not adequately addressed by the private sector.
- From the lab bench towards IND filing, proof-of principle clinical testing and registration or validation.
- Milestone-driven progression of novel cancer preventive chemical or biological agents (singly or in combination) or biomarkers.
- Flexible entry-point system that will optimize and test an agent depending on the stage of development.
- Partnership with successful applicants.
- NCI resources capable of supporting a continuum from initial discovery up to Phase 0/Phase I clinical trials.
EXAMPLE OF AVAILABLE RESOURCES

• *In vitro* and *in vivo* preclinical pharmacology and efficacy studies
• Preclinical Investigational New Drug (IND)-directed GLP toxicology studies
• Identification and evaluation of intermediate biomarkers
• Scale-up non-cGMP and cGMP production of an investigational agent
• PK and PK-PD modeling to optimize dosing regimen
• Formulation optimization for enhanced bioavailability and clinical usefulness
• Analytical method development for investigational agents in bulk form and in biological fluids and tissues
• Stability testing for bulk and formulated material
• Regulatory support
• Other resources to support drug development
WHO

Eligible applicants:

• Researchers in academia, government, industry
• Nationally or internationally.
HOW

Submission deadlines occur twice per year:
First Monday in April and October.

Electronically transmitted (Email) pdf files to:
PREVENT@mail.nih.gov

Submission details listed on the PREVENT website:
http://prevention.cancer.gov/PREVENT
REQUIRED DOCUMENTS

The concept application document should not exceed 5 pages and should outline the scientific nature and rationale of the proposed project and should include the following:

• Background
• Hypothesis
• Research Strategy and Specific Request
• Justification
• Uniqueness

Appendices
• Intellectual Property (IP) Information
• Current Support
• Principal Investigator Biosketch
• Additional Documentation as Appropriate
• Other Appendices
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EVALUATION PROCESS

Criteria
  • Clinical need, feasibility, alignment with NCI mission, novelty, and scientific merit.

Review
  • A panel of external experts (SEP) will review and rank the applications
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PREVENT PRIME CONTRACTORS

In Vitro/In Vivo Development
  University of Alabama
  University of Oklahoma
  IIT Research Institute
  Weill Cornell Medical Center

Efficacy/Intermediate Biomarkers
  Fox Chase Cancer Center
  IIT Research Institute
  SRI International
  University of Oklahoma

Toxicology/Pharmacology
  IIT Research Institute
  Battelle Laboratories
  Southern Research Institute
  SRI International
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<tr>
<th><strong>Vaccines</strong></th>
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<tr>
<td>1. Efficacy of a multi-antigen vaccine in the prevention of MNU-induced <strong>mammary</strong> cancers ER+ in female SD rats</td>
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<td>2. Characterization of potential antigens for immunization against <strong>colon</strong> cancer, and testing multivalent tumor vaccines in min mice.</td>
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<td>3. Plac-1 Vaccine for breast cancer prevention</td>
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<th><strong>Agents</strong></th>
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<td>4. Efficacy of aspirin and naproxen (short-term frequent dosing) in <strong>colorectal</strong> cancer models</td>
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<td>5. Combination of aspirin and Omeprazole for <strong>colorectal</strong> cancer chemoprevention</td>
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<td>6. Preclinical Development of mPGES-1 and 5-LOX selective inhibitors for <strong>colorectal</strong> chemoprevention</td>
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<td>7. Repurposing Itraconazole for topical treatment of basal cell <strong>skin</strong> carcinoma in patients with basal cell nevus syndrome</td>
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<td>8. In vivo evaluation of a chemopreventive agent, ciclesonide, in mouse <strong>lung</strong> tumor model by inhalation</td>
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<td>9. Anti-inflammatory effects of fixed dose combination of Pioglitizone and metformin for <strong>lung</strong> cancer prevention</td>
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<td>10. Chemopreventive effects in both standard chow diets and high fat diets of known positive and negative chemopreventive agents employing both high risk (but histologically normal) mammary epithelium and <strong>mammary</strong> cancer including correlative biomarkers</td>
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<td>11. Modulation of cigarette smoke-induced alterations in microRNA expression and <strong>lung</strong> tumors in mice treated with aspirin and naproxen</td>
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<td>12. Blood-based biomarkers of obesity-induced <strong>breast</strong> inflammation</td>
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QUESTIONS?

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