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PREVENT Cancer Program

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National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

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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.

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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 cGMPproduction 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

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WHO

Eligible applicants:

- Researchers in academia, government, industry
- Nationally or internationally.

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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

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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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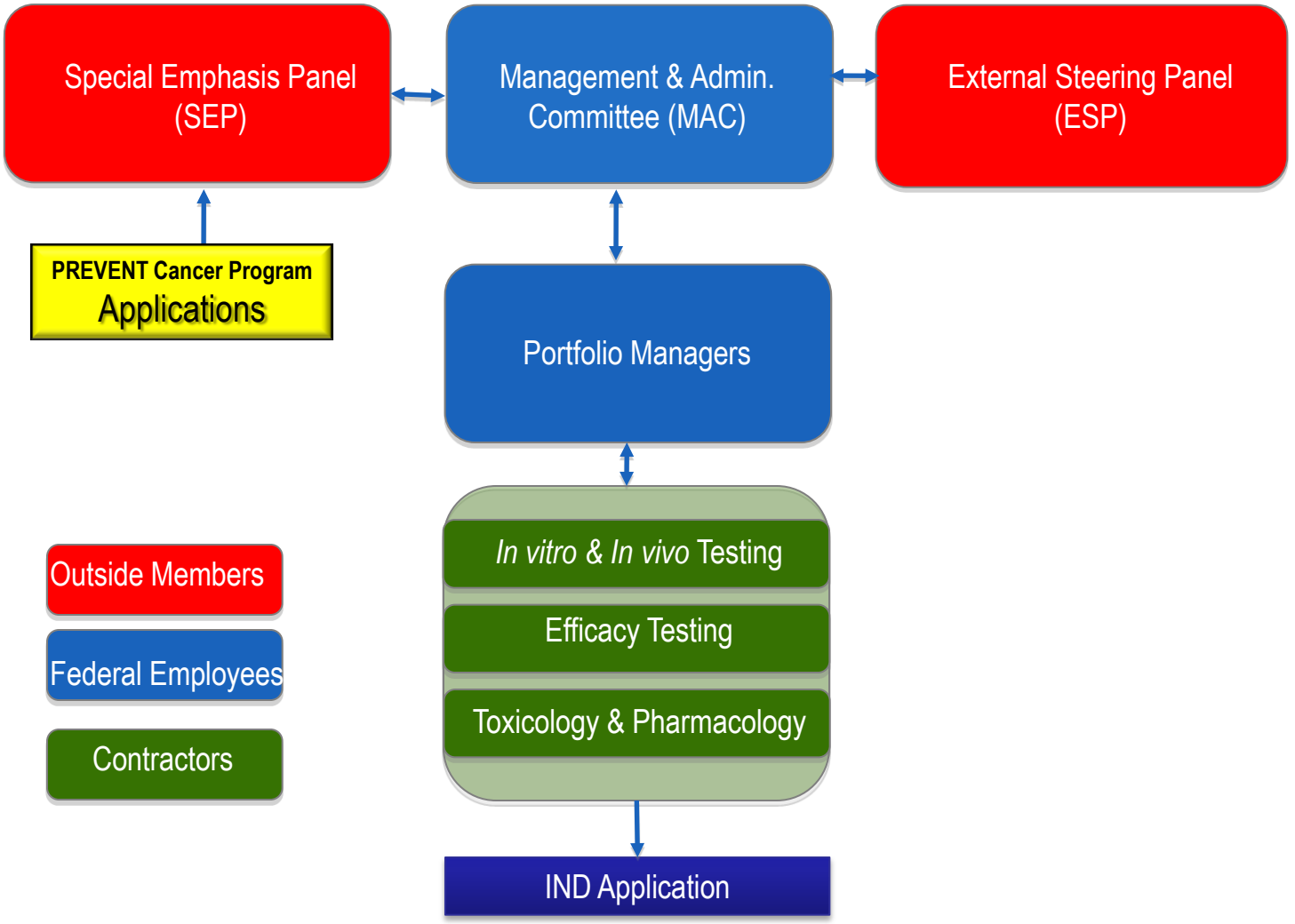

PREVENT Cancer Program: Projects 2012

Vaccines

1. Efficacy of a multi-antigen vaccine in the prevention of MNU-induced **mammary** cancers ER+ in female SD rats
2. Characterization of potential antigens for immunization against **colon** cancer, and testing multivalent tumor vaccines in min mice .
3. Plac-1 Vaccine for breast cancer prevention

Agents

4. Efficacy of aspirin and naproxen (short-term frequent dosing) in **colorectal** cancer models
5. Combination of aspirin and Omeprazole for **colorectal** cancer chemoprevention
6. Preclinical Development of mPGES-1 and 5-LOX selective inhibitors for **colorectal** chemoprevention
7. Repurposing Itraconazole for topical treatment of basal cell **skin** carcinoma in patients with basal cell nevus syndrome
8. In vivo evaluation of a chemopreventive agent, ciclesonide, in mouse **lung** tumor model by inhalation
9. Anti-inflammatory effects of fixed dose combination of Pioglitizone and metformin for **lung** cancer prevention

Biomarkers

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 **mammary** cancer including correlative biomarkers
11. Modulation of cigarette smoke-induced alterations in microRNA expression and **lung** tumors in mice treated with aspirin and naproxen
12. Blood-based biomarkers of obesity-induced **breast** inflammation

QUESTIONS?

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