

OSC Concept Clearance: Ultra-Processed Foods and Health Outcomes – Time to Move Beyond Association to Causation

Background

Diet-related chronic diseases are the leading cause of death worldwide, with over one million deaths in the U.S. per year. They contribute to over \$1.1T in direct health care costs and lost productivity per year. There has been growing interest from both the public and the scientific community for understanding the health impact of ultra-processed food (UPF), which constitutes ~60% of the daily caloric intake in the U.S. and comprises ~70% of the U.S. food supply. Despite epidemiological research suggesting an association between an UPF-rich diet and increased risks for adverse health outcomes, significant research gaps remain in understanding the mechanisms of these relationships. There is also a need for research to explore interventions to reduce unhealthy UPF intake in the U.S. to improve population health.

Program Goal

This program will support robust multidisciplinary research across the lifespan on the mechanisms by which UPF affects chronic disease and provide the evidence base needed to inform dietary guidance, policies, and programs that promote disease prevention.

Initiatives

- **Research & Communications Centers**
 - **Mechanistic:** support research to understand the metabolic, biological, and behavioral mechanisms by which components and combinations of UPF exposure impact health outcomes across the lifespan. Develop and validate biomarkers to understand the role/impact of UPF exposure in various populations. (Note: this initiative would complement and contribute to the new NIH-FDA Nutrition Science Regulatory Program.)
 - **Intervention:** leverage existing and new data to inform the design and conduct of intervention studies, using policy, systems, and environmental approaches and behavioral strategies in various populations to reduce the consumption of UPFs associated with adverse health outcomes/chronic diseases.
 - **Translational Communications:** translate findings from first three years of the program into solution-oriented, scalable, and actionable public health strategies (communications, public/private partnerships); develop educational messages, tools/apps, and resources for consumers and healthcare professionals.
- **Coordination & Analysis Centers**
 - **Nutrient Database & Dietary Analysis:** collect/integrate UPF ingredients and level of processing from existing databases to develop a new UPF database module for consumers/healthcare professionals/researchers and develop novel tools to evaluate UPF intake (including modification of existing tools) to improve rigor/reproducibility of measurements/studies.
 - **Data & Study Coordination:** coordinate/integrate activities of all the Centers, the Nutrient Database, and the Strategic Collaborations and Partnerships.
- **Strategic Collaborations & Partnerships:** this initiative will support opportunities for collaborative partnerships with food scientists and other relevant stakeholders to transform the food supply in the U.S. to optimize effective reformulation strategies to create healthier UPF options.

Deliverables

- A better understanding of the mechanisms through which UPF consumption affects risks for chronic diseases
- Biomarkers for UPF consumption
- Publicly available processed food database module and tools to determine the level of processing and UPF ingredients
- Data to inform interventions specific to UPF consumption and prevention of diseases
- Data to inform FDA regulatory decisions on UPFs, UPF ingredients, and manufacturing processes
- Communication materials to educate the public and health care professionals

Budget (\$300M total over 5 years) Numbers are (\$1000s).

Initiatives	Lead IC(s)	FY2027	FY2028	FY2029	FY2030	FY2031	Total
NIH RMS/Program Management	WG/ICOs	\$1,000	\$1,000	\$1,000	\$1,000	\$1,000	\$5,000
Coordination and Analysis Centers	TBD	\$14,000	\$14,000	\$14,000	\$14,000	\$14,000	\$70,000
Research and Communication Centers	TBD	\$32,000	\$33,000	\$34,000	\$38,000	\$38,000	\$175,000
Strategic Collaborations & Partnerships	TBD	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$50,000
Totals		\$57,000	\$58,000	\$59,000	\$63,000	\$63,000	\$300,000