ILSI North America Lipids Committee Request for Pre-Proposals

Cardiometabolic effects of low carbohydrate/healthy fat diets.

The International Life Sciences Institute (ILSI) North America is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply. The organization carries out its mission by sponsoring relevant research programs, professional education programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to address scientific issues of common concern for the well-being of the public. ILSI North America’s programs are supported primarily by its industry membership.

The Committee addresses emerging issues and trends associated with dietary fats and oils to inform evidence-based nutrition guidance and to improve human health.

ILSI North America adheres to strict procedures to maintain scientific integrity in all work we support. These requirements are described further in the attached TOP Guidelines and 8 Guiding Principles for Scientific Integrity addendums. Pre-proposals meeting the following criteria will be invited to submit a full proposal (which would include detailed research plans, a budget, and timeline).

1. Demonstrated expertise and strong publication record in nutrition epidemiology in the area of cardiometabolic health.

2. Clear scope of work and research approach relevant to the specific questions.

3. Rough cost estimate and realistic timeframe.

Background

Consumers are following many versions of low-carbohydrate diets for perceived health benefits, such as weight loss and improved cardiometabolic health. Industry has responded with new food and beverage products to assist the public eat ‘low carbohydrate.’ There are however many ways to modify one’s diet to consume a low carbohydrate diet, resulting in varying impact on protein content as well as the amount and type of fat. The implications of consumer trending low carbohydrate diets on health outcomes are not well understood, as much of the research to
date on these diets has been tested in controlled research studies which differ from real-life scenarios.

A meta-analysis published in 2020 by Ge et al. compared cardiometabolic health outcomes for up to 1 year in randomized clinical trials of diet programs with differing macronutrient patterns. However, results reflect interventions (not self-selected diets) and group together low-carbohydrate diets regardless of fat intakes (amounts and types). Thus, there is a need to better understand how consumers are implementing, in real life, ‘low carbohydrate’ diets and to differentiate low-carbohydrate diets by lipid intakes (amount and type) as they relate to cardiometabolic health outcomes.


**Research Objective:**
Comparison of cardiometabolic health outcomes associated with self-selected contemporary low carbohydrate diets that differ in macronutrient intake (especially the amount and type of dietary fats).

**Approach**
1. Compare macronutrient intakes (by type and amounts including specific fatty acids) of various contemporary low-carbohydrate diets, based on self-reported intakes in the North American population. Supporting analysis to include characterizing diet patterns based on food restrictions/inclusions and assessing key micronutrient intakes (e.g., sodium), for each specific low carb diet.

2. Determine associations between cardiometabolic health outcomes and contemporary low carbohydrate diets that differ in macronutrient composition, specifically but not limited to amount and type of dietary fat intake. Vascular and brain health are of interest if data are available and additional cost reasonable.

3. Optional: Translate results into predictive algorithms that consumers and health professional can use when making decisions to select a particular ‘low carbohydrate’ diet in order to achieve personalized cardiometabolic goals. There is no a priori approach, tool, or product. Instead, proposals that have a mechanism to incorporate into an existing or in-development application should describe the approach in the proposal. Broad public access to the application will be given preference.

**Additional considerations:**

Out of Scope: Medically prescribed diets.

Pre-Proposal Content:

1. Background: Briefly describe background relevant to the project and proposed approach to address the research need.

2. Research Approach:
   • Overall methodology
   • Questions to be answered
   • Primary and secondary outcomes clearly identified
   • Research approach in broad terms, including the source of data, methods to be used, brief overview of dietary intake data, timeliness of data, and specifics on how self-reported low carbohydrates are reported in the data to be used (including but not limited to the specific diets and reasonable indication of sample size for each diet).

3. Research Team: Principal investigator(s), co-investigators, key team members, and collaborators that may be affiliated but not part of the grant, indicating all potential conflicts of interest.

4. Investigator Credentials: Describe the experiences that make you and your team a candidate for carrying out this project. In addition, the CV of the principal investigator(s) is required. Demonstrated success publishing in this topic area in a quality peer-reviewed journal is a minimum criteria.

5. Estimated budget range and timelines: Please provide the range of budget, noting that ILSI North America limits overhead to 10% of total project costs and journal fees to cover free access (typically US$3,000.00) should be included in the budget. Timelines should include both a presentation of results to committee in-person or by webinar and submit date for a final manuscript in a top tier peer-reviewed journal for publication.

6. References cited:
Pre-proposals are to be submitted to the attention of Barbara Lyle (blyle@ilsi.org) by midnight eastern time July 6, 2020. Pre-proposals should be submitted using the template shown below in the addendums, which is also provided in a separate document for your use.

Addendums

ILSI North America’s Guiding Principles for Funding Food Safety and Nutrition Research

Background
The scientific process requires open, transparent examination and honest interpretation of data, regardless of a researcher’s affiliation or source of funding. To address the potential influence of funding source on scientific research, ILSI North America developed 8 Guiding Principles for Funding of Food Science and Nutrition Research.¹ These guidelines were specifically designed to protect the integrity and credibility of the scientific record. All projects supported by ILSI North America must adhere to these principles.

Guiding Principles for Funding Food Science and Nutrition Research
In the conduct of public/private research relations, all relevant parties shall:

1. Conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome;
2. Require control of both study design and research itself to remain with scientific investigators;
3. Not offer or accept remuneration geared to the outcome of a research project;
4. Ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame;
5. Require, in publications and conference presentations, full signed disclosure of all financial interests;
6. Not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;
7. Guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers;
8. Require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.

Learn more about ILSI North America’s 8 Guiding Principles for Funding Food Science and Nutrition Research here.

Adoption of the Center of Open Science’s Transparency and Openness Promotion Guidelines by ILSI North America

Background
The Center for Open Science's Transparency and Openness Promotion (TOP) Guidelines provide actionable steps for institutions to practice and promote transparent, reproducible, and rigorous research. ILSI North America is a TOP Guidelines signatory. By becoming a signatory, ILSI North America is supporting the principles expressed in the guidelines through their implementation by its funded researchers. The TOP Guidelines include eight modular standards for promoting transparent, reproducible and rigorous research, each with three levels of increasing stringency. Beginning July 1, 2018, all new research studies moving forward will strive to adhere to the levels of the TOP Guidelines specified below, recognizing that this process will take time and effort to achieve.

TOP Guidelines:

1. **Data Citation Standards (Level 3):** Cite shared data. Don’t publish until it is appropriately cited.
2. **Data Transparency (Level 2):** Data must be shared to the maximal extent allowed by ethical and legal constraints.
3. **Analytic Methods (Code) Transparency (Level 2):** Analytic methods (code) must be shared to the maximal extent allowed by ethical and legal constraints.
4. **Research Materials Transparency Level 2):** Materials must be shared to the maximal extent allowed by ethical and legal constraints.
5. **Design and Analysis Transparency (Level 2):** The researcher must use reporting guidelines when writing up publications. Equator-network website provides a huge choice of standards for research designs. [http://www.equator-network.org/](http://www.equator-network.org/) The researcher is asked to select one and register the standard you have selected.
6. **Study Preregistration (Level 2):** When the researcher preregisters his/her study in an independent, institutional registry (e.g., [http://osf.io/](http://osf.io/), [https://www.crd.york.ac.uk/prospero/](https://www.crd.york.ac.uk/prospero/), [http://clinicaltrials.gov/](http://clinicaltrials.gov/)), which is encouraged but not required, ILSI North America will request a third party (e.g., Center for Open Science) verify that preregistration adheres to the specifications for preregistration before data collection.
7. **Analysis Plan Preregistration (Level 2):** When the researcher preregisters his/her study analysis plan in an independent, institutional registry (e.g., [http://osf.io/](http://osf.io/), [https://www.crd.york.ac.uk/prospero/](https://www.crd.york.ac.uk/prospero/), [http://clinicaltrials.gov/](http://clinicaltrials.gov/)), which is encouraged but not required, ILSI North America will request a third party (e.g., Center for Open Science) verify for adherence to preregistered plan (deviations must be transparently reported) before data collection.
8. **Replication (Level 1):** ILSI North America will occasionally put out a call for replication studies as part of our RFP process.

Learn more about ILSI North America's implementation of the TOP Guidelines [here](http://www.equator-network.org/).

Template

ILSI NA Pre-Proposal on Cardiometabolic effects of low carbohydrate/healthy fat diets.
(2-page maximum, single space, 11 font minimum)

Date: ____________

**Lead Investigator, affiliated organization for the grant, email, phone**

<table>
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<th>Overview of approach (1-3 sentences)</th>
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**Background** (1-3 sentences)

**Primary hypothesis**
- X

**Secondary hypotheses**
- X
- Y
- Z

**Research approach**

**Investigator credentials of PI, co-PI, co-investigators, and collaborators**

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation (Institution and department)</th>
<th>Disclose potential conflicts of interest and all funding sources over $5,000 (2014+)</th>
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**Attach PI/co-PI CV or NIH biosketch**

**Estimated budget and timeline**
Range with a clear estimated upper limit to costs inclusive of all direct and indirect costs (the latter of which are limited to 10%) including free access publication fees ($3,000) =

Estimated maximum time from agreement to submitted manuscript for publication =