



# Exploring the health effects of consuming soy foods made using concentrated sources of soy protein

## Request for Letters of Intent

Soy Nutrition Institute Global (SNI Global) requests letters of intent from parties interested in conducting clinical research involving healthy adults designed to evaluate the health effects of consuming soy foods made with concentrated sources of soy protein. Primary endpoints should be determined by the investigating team but of particular interest are outcomes that relate to the proposed adverse health effects of foods classified by Nova as ultra-processed. Trials in which at least some of the test foods are provided by the researchers and which carefully monitor overall dietary intake are considered most desirable. The proposed research can include clinically relevant markers of disease risk (e.g., LDL-cholesterol, blood pressure, insulin sensitivity) as well as less established markers such as changes in the microbiome, telomere length and DNA methylation. Mechanistic work is of particular interest, including but not limited to outcomes related to the proposed mechanisms by which ultra-processed foods are thought to exert adverse health effects (e.g., hyper-palatability, fast eating rate, low satiety value, increased intestinal permeability)

It is anticipated that up to \$800,000 (USD) of total funds will be available for the proposed research. Funds will be distributed over a three-year period. The study must be completed and the resulting manuscript submitted for publication to a peer-reviewed journal by September 30, 2027. Additional grant funding may be available if additional outcomes or endpoints are negotiated with SNI Global.

### SUBMISSION GUIDELINES

Interested researchers should submit a completed application form and a letter of intent. Successful applications will be from multidisciplinary teams who have experience conducting the planned research. The letter of intent should describe study design, study participants, study intervention (duration, dose, and delivery vehicle for soy protein and, if applicable, the control product) and outcome measures (primary and secondary). The letter of intent can include more than one study, as long as the total budget does not exceed \$800,000.

The letter of intent should be approximately two pages in length and should include three sections:

1. Brief qualifications of the investigator(s) and their affiliated institution(s) as they relate to the proposed research (detailed information on qualifications, such as the curriculum vitae or NIH biosketch of the principal investigator, can be sent as an addendum);
2. The experimental design including endpoints to be tested; and
3. Proposed budget

Please note:

- Funding for this study will be provided by the United Soybean Board (USB), with screening and evaluation of proposals provided by SNI Global on behalf of the USB. Contract and administration details will be provided by SNI Global.
- These items may *not* be included in the proposed budget:
  - Indirect costs
  - Purchase of capital equipment, although leasing costs may be included
  - Salary of principal investigator or co-investigator

**The deadline for the submission of the application form and letter of intent is June 7, 2024.**

## **TIMELINE**

- **June 7, 2024** -- Deadline for submission of application form and letter of intent.
- **June 28, 2024** -- Based on the letters of intent, SNI Global will send requests for expanded full proposals and detailed budget information from selected research groups.
- **August 2, 2024** -- Deadline for submission of full proposals by selected research groups.

After reviewing the expanded proposals, SNI Global will select up to one group with whom to enter into contract negotiations. At that time, details of the experimental design can be finalized.

## **SUBMISSION DETAILS**

Application form and letter of intent should be sent to Kaci Vohland, MS, RDN, Project Manager, Scientific Affairs and Research, SNI Global, at: [kaci.vohland@sniglobal.org](mailto:kaci.vohland@sniglobal.org). Questions prior to submission can be addressed to Mark Messina, PhD, MS, by email or phone at [mark.messina@sniglobal.org](mailto:mark.messina@sniglobal.org) or 413-464-0565.

## **BACKGROUND**

In recent years there has been increased focus on the role that processing has on the healthfulness of food independent of nutrient composition. Much of this interest stems from the emergence of the Nova food classification system, which was created in 2009.<sup>1</sup> Under this system, all foods are classified into one of four categories based entirely on the degree to which they have been processed.<sup>2</sup> Group 1 foods (unprocessed/minimally processed) are the least processed whereas group 4 foods (ultra-processed) are the most processed. Proponents of Nova discourage the consumption of ultra-processed foods (UPFs) and encourage the consumption of unprocessed/minimally processed foods.

Americans consume approximately 58% of calories from UPFs, which is a higher percentage than for most developed countries and markedly higher in comparison to developing countries.<sup>3</sup> Numerous epidemiologic studies have identified associations between UPF intake and a range of adverse health outcomes, including obesity, dementia, diabetes, depression, certain cancers and cardiovascular disease.<sup>4,5</sup> There is also a growing movement commonly referred to as the “clean eating movement” that generally aligns with Nova.<sup>6,7</sup> Although there is no precise definition, the clean eating concept stresses the importance of eating foods as close as possible to their natural state and avoiding heavily processed foods that contain synthetic ingredients, and are high in fat, sugar, sodium, preservatives, food dyes, and other additives.

Nova and the clean eating movement directly impact the perception of many soy foods because all products containing concentrated sources of soy protein, such as soy protein isolate and soy protein concentrate, which are approximately 90% and 65% protein on a weight basis, respectively, are classified as UPFs. Also, 90% of all plant milks, including soymilk made from whole soybeans, are considered ultra-processed.<sup>8</sup> Within the scientific community, there is increasing recognition that all UPFs are not nutritionally similar.

In fact, observational research shows that while total UPF intake is often associated with adverse health outcomes, subgroups of UPFs are often not associated with risk or are associated with a decreased risk.<sup>9-15</sup> For example, a recently published analysis of a multinational cohort found that higher UPF consumption was associated with an increased risk of multimorbidity of cancer and

cardiometabolic diseases. However, whereas ultra-processed animal-based products and artificially and sugar-sweetened beverages were associated with marked increased risks, plant-based alternatives were associated with a non-significant decreased risk.<sup>9</sup> Similarly, although a combined analysis of 3 large US cohorts found total UPF intake was associated with an increased risk of developing diabetes, the hazard ratio for 7 of the 14 subgroups of UPF was below 1.00 (indicating a protective association).<sup>10</sup> Three clinical trials have also shown that plant meats classified as ultra-processed do not exert adverse health effects relative to their meat-based counterparts.<sup>21-24</sup>

Furthermore, there is substantial evidence supporting the health benefits of concentrated sources of soy protein. In addition to being of high quality,<sup>16</sup> soy protein directly lowers blood cholesterol levels<sup>17,18</sup> and promotes gains in muscle mass and strength in individuals undergoing resistance exercise to the same extent as animal protein including whey.<sup>19</sup> Also, a recent analysis in which soymilk (ultra-processed) was compared with cow's milk (unprocessed/minimally processed), and soy burgers (ultra-processed) with beef burgers (unprocessed/minimally processed), showed that the soy products do not possess any of the undesirable attributes associated with UPFs more so than their dairy and meat-based counterparts.<sup>20</sup> Attributes considered for this analysis included energy density, palatability, eating rate, energy intake rate, satiety, cost, snackability/ convenience, and glycemic index. Overall, there is little scientific basis for suggesting that foods containing concentrated soy protein cannot make an important contribution to the diet.

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***ABOUT SOY NUTRITION INSTITUTE GLOBAL***

Soy Nutrition Institute Global is a global scientific voice of soy for human health and nutrition. SNI Global leads the way in soy and health research, outreach and communications, and government and regulatory affairs. The organization includes members up and down the soy value chain – from farmers to food companies – as well as a scientific advisory board that provides expert guidance in various areas of nutrition science. For more information about the Soy Nutrition Institute Global, visit [www.SNIGlobal.org](http://www.SNIGlobal.org).



# Research Project Application



Funding: 10/1/2024 – 9/30/2027

Project Title:	
Principal Investigator Name:	
Principal Investigator Title, Employer:	
Mailing Address:	
City/State/Zip:	
Telephone Number:	Email Address:

Co-Investigator Name:
Co-Investigator Title, Employer:
Co-Investigator Name:
Co-Investigator Title, Employer:

***\*Use additional page if needed***

**Funding Requested:**

Total Funding:	Year 1: (10/1/24 – 9/30/25)	Year 2: (10/1/25 – 9/30/26)	Year 3: (10/1/26 – 9/30/27)
\$	\$	\$	\$

List of Project Partners, Institutions, Organizations, Businesses & Agencies: <i>(Use additional page if needed.)</i>
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Principal Investigator:	Authorized Organizational Representative:
Signature:	Signature:
Date:	Date:

Send completed form to Kaci Vohland with SNI Global at [kaci.vohland@sniglobal.org](mailto:kaci.vohland@sniglobal.org).