

IAFNS Nutrition for Gut Health Committee Request for Proposals March 2024

Advancing Research that Supports 'Gut Health': Documenting the Continuum of Measures from Health to Disease

The Institute for the Advancement of Food and Nutrition Sciences (IAFNS) is a non-profit, 501(c)(3) scientific organization that pools funding from industry collaborators and advances science through the in-kind and financial contributions from public and private sector participants.

The IAFNS Nutrition for Gut Health Committee advances the scientific understanding of the impact of diet and dietary constituents on gut and host health.

IAFNS adheres to rigorous procedures to maintain scientific integrity in all work we support. These requirements are described further in the attached Transparency and Openness Promotion (TOP) Guidelines and 9 Guiding Principles for Scientific Integrity addendums.

Background

In a 2011 paper titled "Gut health: A new objective in medicine?" (Bischoff), it was noted that gut health is recognized as a "desirable aim and an important physiological condition required for overall good health." Since the gut microbiome research boom which was initiated shortly after this paper, even more attention has been focused on the gut as impactful to health — across many systems. The gut is the location of the majority of the immune system, is central in gutbrain axis effects, controls systemic access of dietary nutrients and other substances. In addition, subjective symptoms (bloating, constipation, flatulence) can impact day-to-day quality of life of individuals.

Although the concept of a "healthy gut microbiome" remains elusive, there do exist objective and subjective measures of gut function which are indicative of health and disease. For example, there exist various validated physiological indicators of inflammation, motility (Camilleri and Linden, 2016), or permeability (Mishra and Makharia, 2012; Koshbin et al. 2021), and subjective assessment of e.g., discomfort, bowel habits (Lacy and Patel, 2017), and others. Although it is implied that "gut health" lies somewhere along the continuum of each of these measures, there is currently no generally accepted definition of gut health. The 2011 paper discusses the lack of a consensus definition and offers a table of assessments or measures.

One step toward arriving at agreement on the concept of 'gut health' is better understanding available measures and their interpretation, starting with an update of the Bischoff work. By clarifying this concept, it may be possible to identify interventions (foods, diets, supplements) that promote gut health.



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References

Bischoff. 2011. Gut health: A new objective in medicine. BMC Medicine. 9 (24). Accessible at: https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-24.

Camilleri M and Linden DR. 2016. Measurement of Gastrointestinal and Colonic Motor Functions in Humans and Animals. Cell Mol Gastroenterol Hepatol. 2(4): 412–428. Accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5026190/pdf/main.pdf.

Koshbin et al. 2021. Development And Validation Of Test For 'Leaky Gut' Small Intestinal And Colonic Permeability Using Sugars In Healthy Adults. Gastroenterol. 161(2): 463-475. Accessible at: https://www.sciencedirect.com/science/article/pii/S0016508521006429.

Lacy BE and Patel NK. 2017. Rome Criteria and a Diagnostic Approach to Irritable Bowel Syndrome. J Clin Med. 2017 Nov; 6(11): 99. Accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5704116/.

Mishra A and Makaharia GK. 2012. Techniques of Functional and Motility Test: How to Perform and Interpret Intestinal Permeability. J Neurogastroenterol Motil. 18(4): 443–447. Accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3479259/pdf/jnm-18-443.pdf.

Objective

The goal of this project is to collate, summarize, and publish measures or indicators of 'gut health' that are currently applied across domains ranging from academia, to healthcare, to inform the characterization of, as well as research and interventions to support, a healthy state.

The audience for this work includes researchers looking to investigate the impacts of foods or ingredients on the gut, the R&D segments of food or supplement companies looking to develop products beneficial to gut health, and healthcare practitioners looking to better understand what 'gut health' means and how it is measured.

The committee envisions a systematic approach to collection and review of publicly available information to include accepted medical practices and policies, peer-reviewed literature, and qualitative measures or scales related to gut symptomology or gut function.

The final product will be a peer-reviewed publication, the results of which can be communicated through other platforms such as webinars or scientific meetings.

Proposal Content

The Committee requests that applicants address each of the following components below in their proposal, which should be not more than 5 pages single-spaced (investigator CVs and/or example publications can be provided separately):

1. Background: Briefly describe the literature relevant to the project question and how the proposed review addresses the project goals.

2. Research Approach:

• Specify the question(s) to be addressed.



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- Research approach <u>in broad terms</u>, including the source of information, search methods, search terms, and how the information will be presented.
- Note that researchers will be required to follow the IAFNS openness and transparency guidelines, as noted in the TOP addendum.

Additional notes for the approach:

- It may be useful to classify the measures into specific domains, e.g., cancer assessment, inflammation, motility, nutrient absorption.
- Due to the potential for some information to be from older sources, the search should not be limited by date.
- Resources beyond the peer-reviewed literature may be considered, such as books, book chapters, practice documents (e.g. medical or other healthcare practitioner), white papers, unpublished (dissertation) research or authoritative reports.
- The documentation should include thresholds/cutoff points for measures, documentation of validity (and the type of study), documentation of ranges reflective of a healthy/normal state through what would be considered reflective of disease.
- Age is not limited, and it would be interesting to document if the measures are intended for use in specific age subgroups or if the thresholds for normal/healthy/disease are different.
- Information on the impact of nutrition should be limited to documenting whether this has been studied (yes/no).
- Review by clinical experts for appropriateness and completeness is requested. Ideally
 this review is conducted by e.g. a professional society committee. IAFNS can assist
 with making this connection but we are open to ideas.
- In Scope:
 - o Information available in the public domain.
 - o Both objective and subjective measures of gut health are used in clinical practice, in research, or as described by consumers.
 - Disease-related markers will be considered in-scope to understand the range reflective of a healthy state.
 - o The measures should be relevant to the luminal gastrointestinal tract.
- Out of scope:
 - Measures that at present are not interpretable as related to health (e.g., reflecting gut microbes or gut metabolites).
 - o Measures relevant beyond the luminal gastrointestinal tract.
- Anticipated Challenges: Describe any anticipated challenges that may be encountered.
- **4. Publication Plan:** The Committee wishes the researchers to publish this work in a peer-reviewed journal. Please provide your suggested publication plan.
- **5. Research Team:** Principal investigator(s), co-investigators, key team members, and collaborators that may be affiliated but not part of the grant.
 - 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 (not included in the page limit).



- Demonstrated success publishing in this topic area in a quality peer-reviewed journal is a minimum criterion.
- 6. **Resources:** Please describe the resources you have available to complete the project.
- 7. **Estimated Budget, Timeline, and Key Deliverables:** Timelines should include a mid-point virtual progress report, a virtual presentation of final results to the committee, and a submit date for a final manuscript in a top tier peer-reviewed journal for publication. Timeline from initiation to final manuscript draft should be in the range of 9-12 months.
 - Please provide a proposed budget (a range is acceptable).
 - Please itemize the budget as appropriate and feasible.
 - Note that IAFNS limits institutional overhead or indirect costs to 10% of total project costs.
 - Publication costs do not need to be included as IAFNS will support this separately.
- **8. Potential Conflicts of Interest:** List any potential conflicts of interest for all investigators, co-investigators, collaborators.
 - We suggest using the Conflict of Interest Guidelines noted here: https://declarations.elsevier.com/

9. References

Additional Considerations

In addition, as you prepare your proposal, please note the following points:

- Attachments such as reprints of scientific papers and budgets are discouraged. This
 information will be required later if a full proposal is requested.
- There is no restriction regarding either the citizenship of applicants or the country where the research will be conducted. However, all submitted documents must be in English.
- Receipt of a research grant does not preclude the recipient from obtaining grant support in the same or similar area from other sources.
- Grants awarded under this program are typically approved for up to a one-year period. In exceptional cases, funding for an additional 6 months may be considered.

Page Limit: 5 pages, single spaced (not including PI's CV)

Proposal Submission Deadline: Midnight, April 19, 2024. A brief note of intention to apply is also requested to mlatulippe@iafns.org.

Submission Instructions: Proposals (and questions) can be submitted to Marie Latulippe (mlatulippe@iafns.org).

Review Process: A review committee composed of scientists from academia, government, and industry will evaluate the proposals. It is anticipated that applicants will be notified of the status of their proposals within a few weeks following the submission deadline.



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Proposals will be assessed for 1) Impact relative to the stated project objectives, 2) Demonstrated expertise and publishing record for the PI and team, and 3) Reasonable range of time and budget.

Critiques of individual proposals cannot be provided.



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Addendum IAFNS's Guiding Principles for Funding Food Science 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. The following Guiding Principles¹ address the potential influence of funding source on scientific research. All projects supported by IAFNS 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; according to accepted principles of scientific inquiry, the research design will investigate an appropriately phrased hypothesis and/or question, rather than favor a particular outcome;
- 2. Require control of the study design, the research itself, and the interpretation of findings to remain with scientific investigators;
- 3. Not offer or accept remuneration geared to the outcome of a research project;
- 4. Prior to the commencement of studies, ensure that there is a written agreement that the investigative team has an obligation to attempt to publish the findings within some specified timeframe and the freedom to choose the journal to which the work will be submitted;
- 5. Require, in publications and conference presentations, full written or oral disclosure, as appropriate of all relevant relationships (financial and non-financial competing interests);
- 6. Not participate in undisclosed authorship arrangements in publications or presentations;
- 7. Guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/peer reviewers; when possible, encourage the practice of open science, including depositing data and methodology on a public repository;
- 8. Require that academic researchers, when they work in contract research organizations or act as contract researchers, make clear statements of their affiliation; require that such researchers publish under the auspices of the contract research organization;
- 9. Require, in publications and conference presentations, disclosure of whether the funder advised on the study design, conduct of research and/or the development of the manuscript.





Adoption of the Center of Open Science's Transparency and Openness Promotion Guidelines by IAFNS

<u>Background</u>: The Center for Open Science's <u>Transparency and Openness Promotion (TOP)</u> <u>Guidelines</u> provide actionable steps for institutions to practice and promote transparent, reproducible, and rigorous research. IAFNS is a TOP Guidelines signatory. By becoming a signatory, IAFNS 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.

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/ 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/, http://clinicaltrials.gov/), which is encouraged but not required, IAFNS 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/, http://clinicaltrials.gov/), which is encouraged but not required, IAFNS 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):** IAFNS will occasionally put out a call for replication studies as part of our RFP process.