HESI PROPOSAL FORM

Return no later than ***4 December 2015***
to Cyndi Nobles at cnobles@hesiglobal.org (fax: 202-659-3617).

Instructions:

- Consult / coordinate with colleagues in other divisions / departments within your institution to solicit and propose ideas on human health and environmental issues of concern.
- Use a separate form for each topic and additional pages, if needed.

Submitter name, affiliation, phone, and email:

Donna Mendrick, FDA/NCTR; 301-796-8892, donna.mendrick@fda.hhs.gov

Is this proposal submitted on behalf of more than one person / institution? If yes, identify co-submitters below.

Suzy Fitzpatrick, FDA/CFSAN; Suzanne.Fitzpatrick@fda.hhs.gov

Proposal title:

Role of microbiome in human health

Key words: *(minimum of two)*

microbiome, microbiota

Describe the problem to be addressed. Why is the issue important? To whom is this issue important?

It is becoming well-recognized that the microbiome plays important roles in the maintainence of health and is modified during development and exposure to new environments such as living in different countries, food intake, drug exposure,etc. In animals and humans it has been shown that transplants of intestional microbiota conveys the phenotype of the donor (e.g., can make a lean animal/human gain weight even when food intake is not changed.) We are just beginning to understand some of its actions yet much remains to be know. For example, what is "normal?" What probiotics should one take to remain or return to "normal?" This issue impacts human medicine, environmental risk management, etc.

Describe the basic project steps or stages to the best of your ability, including an expected timeline, milestones, and deliverables for the first two years.

This is a very broad topic so first it will be important to focus one an area of mutual interest. For example, response to drugs and environmental toxicants or definition of what constitutes "normal" and how to return to it.
The second step would be to perform literature reviews to identify the state of the art.
The third step would be to identify data gaps and design discrete experiments
Time line:
0-3 months: identify topic(s)
3-9 months: literature search
9-12 months: identify important, attainable data gaps
year 2-3: design and carry out experiments
Deliverables: paper and presentations on state of the art. Paper and presentations on research findings

What is the potential or anticipated impact of successfully achieving the milestones described above? *(Describe scientific, regulatory, policy, public health, and/or other impacts.)*

This will depend on the focus the group decides to pursue however, in either case it should improve our understanding of the role of the microbiome on human health

Describe the interdisciplinary, collaborative nature of the proposed project, and identify potential partners: *(identify institutions, organizations, companies, and or consortia)*

This is a multidisciplinary project that would require individuals skilled in microbiology, toxicology, etc. Institutions that should be interested would include the FDA, NIH, EPA, pharmaceutical and nutraceutical companies, food producers, and dietary supplement manufacturers.

How did you hear about HESI's proposal solicitation? (e.g., HESI email or website, society announcement)

HESI email

Other comments.

Return no later than ***4 December 2015***
to Cyndi Nobles at cnobles@hesiglobal.org (fax: 202-659-3617).

QUESTIONS?

Contact:
Jennifer B. Pierson, MPH
HESI Scientific Program Manager
jpierson@hesiglobal.org
202-659-3306, x158