# The Gut Microbiome as a Paradigm for the Opportunities and Challenges of Human Subject Research

Sept. 26–27, 2018

Organized by the Digestive Disease Research Centers  
Hosted by the Perelman School of Medicine at the University of Pennsylvania  
Supported by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health and the American Gastroenterological Association

## PROGRAM AGENDA

### DAY 1

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<th>Time</th>
<th>Event</th>
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<tr>
<td>8–8:15 a.m.</td>
<td>Introductions</td>
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<td>8:15–9 a.m.</td>
<td>Keynote: Eric Alm, MIT</td>
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**Session 1: Paradigm for the Translation of Research from the Bench to the Bedside**  
9–9:20 a.m.  
The Value of Animal Model Systems in Demonstrating Proof-of-Concept in the Functionality of the Gut Microbiome  
R. Balfour Sartor, MD

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| 9:20–9:40 a.m.| The Gut Virome from Bench to Bedside  
Scott Handley, PhD |
| 9:40–10 a.m.  | What Type of Human Interventions in the Gut Microbiome Can be Performed in Human Subjects/Patients?  
Gary D. Wu, MD, AGAF |
| 10–10:30 a.m. | Panel Discussion                                                      |
| 10:30–10:45 a.m.| Break                                                             |

**Session 2: Paradigm for Translation from Clinical Research to the Bench**  
10:45–11:05 a.m.  
Cross-Sectional Human Gut Microbiome Studies for Hypothesis Generation  
Bernd G. Schnabl, MD, AGAF

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| 11:05–11:25 a.m.| The Value of Prospective Longitudinal Human Cohort Studies on Gut Microbiome: What Have We Learned and What are the Limitations?  
Cynthia L. Sears, MD |
11:25–11:45 a.m. The Bedside-to-Bench Paradigm of Human Gut Microbiome Research
Eugene B. Chang, MD, AGAF

11:45 a.m.–12:15 p.m. Panel Discussion

12:15–1:45 p.m. Break

**Session 3: High-Throughput Platforms for Hypothesis-Generating Research**
1:45–2:05 p.m. Microbes, Metabolites and Mucosal Systems
Ramnik J. Xavier, MD, PhD, AGAF

2:05–2:25 p.m. Metabolomics in Gut Microbiome Research
Andrew D. Patterson, PhD

2:25–2:45 p.m. New Techniques: Proteomics
Janet K. Jansson, PhD

2:45–3:15 p.m. Panel Discussion

3:15–3:30 p.m. Break

**Session 4: Integration of Datasets Through Computational and Biostatistical Tools**
3:30–3:50 p.m. EHR as a Data Collection Tool
Peter D. R. Higgins, MD, PhD, MSc

3:50–4:10 p.m. Quantifying the Human Response to the Gut Microbiome
Ashwin Ananthakrishnan, MD, MPH

4:10–4:30 p.m. Data Integration, Systems Biology, and Precision Medicine
Georg Gerber, MD, PhD, MPH

4:30–5 p.m. Panel Discussion

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**DAY 2**

**Session 5: Human Subjects Research**
8–8:20 a.m. Design Considerations in Human Intervention Studies
James D. Lewis, MD, MSCE, AGAF

8:20–8:40 a.m. A Primer on Human Subjects Research
Loren Laine, MD, AGAF

8:40–9 a.m. From Serendipity to Improvement of Human Health: the Development of FcRn-based Therapeutic Agents
Richard S. Blumberg, MD, AGAF

9–9:30 a.m. Panel Discussion
9:30–9:45 a.m.  Break

**Session 6: How to Organize and Support Team Research in Humans**

9:45–10:05 a.m.  Building a Team and the Role of Clinicians  
Scott B. Snapper, MD, PhD

10:05–10:25 a.m.  Identifying and Utilizing Resources Available Through the NIH Clinical and Translational Science Awards  
Garret A. FitzGerald, MD

10:25–10:45 a.m.  Partnerships with NIH, Foundations and Industry  
Scott Plevy, MD

10:45–11:15 a.m.  Panel Discussion

11:15 a.m.–12 p.m.  Wrap Up Discussion

**Learning Objectives**

1. Understand how basic research can be translated to the bedside, and how clinical research can be leveraged for further basic biological discovery.
2. Describe the technological platforms and "big datasets" that can be used to generate hypotheses for new research.
3. Explain the considerations in design, oversight, and execution of human subjects research related to the gut microbiome.

**Organizing Committee:**

- Gary D. Wu, MD, AGAF, Chair
- Jorge A. Bezerra, MD, AGAF
- Nicholas O. Davidson, MD, DSc, AGAF
- Mark Donowitz, MD, AGAF
- Hashem B. El-Serag, MD, MPH
- Wayne I. Lencer, MD, AGAF
- Jacquelyn J. Maher, MD
- Richard M. Peek, Jr., MD, AGAF
- Robert S. Sandler, MD, MPH, AGAF
- Allan W. Wolkoff, MD, AGAF
- Ramnik J. Xavier, MD, PhD, AGAF