Human Microbiome Research and the Social Fabric

Rosamond Rhodes, Lily Frank, Nada Gligorov, & Abraham Schwab

This presentation is licensed under the Creative Commons Attribution 3.0 Unported License available at http://creativecommons.org/licenses/by/3.0/
Forthcoming Book with Oxford University Press

Table of Contents

- Scientific Background
- Self –Identity
- Privacy
- Property
- Research
- Public Health
- Biobanks
Approach and Methods – A process of self-education and interdisciplinary conversations to:

- Evaluate relevant current thinking about ethical, legal and social issues through the lens of microbiome research in order to see these issues from a new perspective.

- Compare ethical issues raised by microbiome research to issues raised by other recent scientific inquiries.

- Develop consensus recommendations related to the ethical, legal and social implications of human microbiome research that we can foresee.
30 Interdisciplinary Participants

Jody Azzouni, PhD, philosophy
Mark Babyatsky, MD, gastroenterology
Mary Ann Baily, PhD, economics
Stefan Baumrin, PhD, JD, philosophy, law
Keith Benkov, MD, pediatric gastroenterology
Martin Blaser, MD, microbiology
Erwin Bottinger, MD, systems therapeutics
Barbara Brenner, Dr PH, MSW, sociology
Joseph Dauben, PhD, history
Bill Earle, PhD, philosophy
Lily Frank, MA, philosophy
Nada Gligorov, PhD, philosophy
Joseph Goldfarb, PhD, pharmacology
Kurt Hirschhorn, MD, genetics
Rochelle Hirschhorn, MD, genetics
Ian Holzman, MD, neonatology
Debbie Indyk, PhD, sociology
Ethylin Jabs, MD, genetics
Douglas Lackey, PhD, philosophy
Daniel Moros, MD, neurology
Sean Philpott, PhD, MSB, microbiology
Matthew Rhodes, ABD, microbiology
Rosamond Rhodes, PhD, philosophy
Lynne Richardson, MD, emergency medicine
Henry Sacks, PhD, MD, preventive medicine
Abraham Schwab, PhD, philosophy
Rhoda Sperling, MD, gynecology
Marie Teil, biobank
Brett Trusko, MBA, PhD, business, informatics
Arnulf Zweig, PhD, philosophy
Chapter Teams
Team Leaders

**Background**
Lily Frank, MA
Mark Babyatsky, MD
Keith Benkov, MD
Martin Blaser, MD
Kurt Hirschhorn, MD
Ian Holzman, MD
Sean Philpott, PhD
Matthew Rhodes, ABD
Rhoda Sperling, MD

**Personhood**
Nada Gligorov, PhD
Jody Azzouni, PhD
Mark Babyatsky, MD
Ian Holzman, MD
Douglas Lackey, PhD
Rhoda Sperling, MD
Arnulf Zweig, PhD

**Biobanks/Sample Banks**
Abraham Schwab, PhD
Erwin Bottinger, MD
Sean Brady, Ph
Barbara Brenner, DrPH, MSW
Joseph Goldfarb, PhD
Rochelle Hirschhorn, MD
Sean Philpott, PhD
Marie Teil

**Public Health**
Rosamond Rhodes, PhD
Stefan Baumrin, PhD, JD
William Earle, PhD
Daniel Moros, MD
Lynne Richardson, MD
Henry Sacks, MD

**Research**
Rosamond Rhodes, PhD
Keith Benkov, MD
Martin Blaser, MD
Joseph Dauben, PhD
Sean Philpott, PhD

**Privacy**
Nada Gligorov, PhD
Stefan Baumrin, PhD, JD
Debbie Indyk, PhD
Ethylin Jabs, MD
Key Recommendations: Self–Identity

- Science influences what we think. The HMP is likely to reshape our notions of self-identity somewhat.

- The HMP is unlikely to effect philosophical conceptions of the personal identity problem.
Key Recommendations: Self -Identity

- It may change our concept of the human organism and affect the distinction between us and our environment.

- It is also likely to transform how we think of the microbes on and in our body, from enemies that must be eradicated to entities that are important in maintaining health.
Negative view of microbes
Positive View of Microbes
Key Recommendations: Self–Identity

- To foster research, we should take care how the public is educated about the microbiome and its effects on human health.

- Clinicians and researchers need to be mindful when developing language to describe microbial inhabitants.
Key Recommendations: Privacy

“Privacy,” should be distinguished from the concept of medical “confidentiality.”

In treatment and biomedical research, information about people’s microbiome should be treated according to standards of confidentiality that govern other medical and research interactions.
The Genetic Information Nondiscrimination Act (GINA) should be extended to cover the human microbiome.
- Health insurance
- Employment

Samples collected for research should be safeguarded from criminal and immigration investigations.
- Biobanks and sample banks should be subpoena proof.
The concept of “property” is socially constructed.

Some features of the microbiome make us think of it as property:
- it is in or on your body
- obtaining some samples require permission

Other features of the microbiome do not make us think of it as property:
- discarded items
- things we don’t value at all (e.g., dandruff)
Key Recommendations: Property:

- Property law is a dynamic patchwork

- Laws and policies related to the use and ownership of the microbiome and derivative applications should be carefully designed:
  - to avoid undermining important social projects (e.g., biomedical knowledge)
  - to promote social goods (e.g., improved health and medical care).
The distinction between “innovation” and “research” is not clear.

Clinicians may offer an innovative treatment to patients with no oversight, & when the very same intervention is studied, restrictions and requirements are imposed.

Not all studies require the same level of oversight.

Institutional gatekeeper boards should be established to determine which scientific studies require IRB review based on risk.
Key Recommendations: Research

• Payment to induce participation and study completion is not morally objectionable when the study itself is determined to be ethically sound.

• Inducements may be used to encourage:
  - Study participation
  - Compliance with repeated follow-up
Key Recommendations: Public Health

- The current regulatory definition of “research” distinguishes it from “public health surveillance,” “QI,” and “QA.”
  - These are all scientific activities.
  - They all produce “generalizable knowledge.”
  - They all use the same techniques.

- Ethical oversight and restriction should be based on factors about the study and its involvement of human subjects such as risk, need to know, urgency, possible harms and benefits.

- The distinction should not turn on the researcher’s “intention.”
Key Recommendations: Biobanks

Basic research using microbiome biobanks and sample banks will pose only *de minimis* risk, and knowledge gained from studies will be broadly applicable, hence:

- participation in studies should be encouraged.
- specified informed consent for future uses of samples should not be required.
- remaining samples from clinical care may be used without informed consent.
Key Recommendations: Biobanks

Institutions should establish mechanisms to promote community trust:

- Oversight boards to review and approve all studies using collected samples.
- Process consent allowing sample contributors to agree to the institutional process governing sample use.
- Transparency through communication with contributors about biobank activities.
Conclusion

- Scientists are just beginning to understand our microbial selves.
- The HMP gives us an opportunity to re-examine ethical, legal and social issues in biomedical ethics from a fresh perspective.