

Human Microbiome Research and the Social Fabric

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

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Forthcoming Book with Oxford University Press

Table of Contents

- Scientific Background
 - Self –Identity
 - Privacy
 - Property
 - Research
 - Public Health
 - Biobanks
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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.
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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

Property

Abraham Schwab, PhD

Mary Ann Bailey, PhD
Kurt Hirschhorn, MD
Brett Trusko, PhD

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

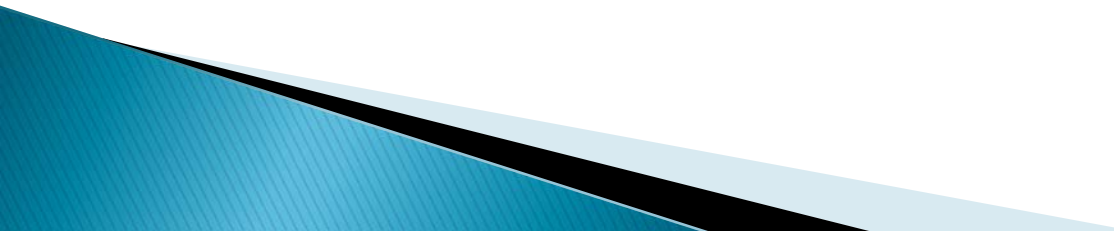
Keith Benkov, MD
Martin Blaser, MD
Joseph Dauben, PhD
Sean Philpott, PhD

Privacy

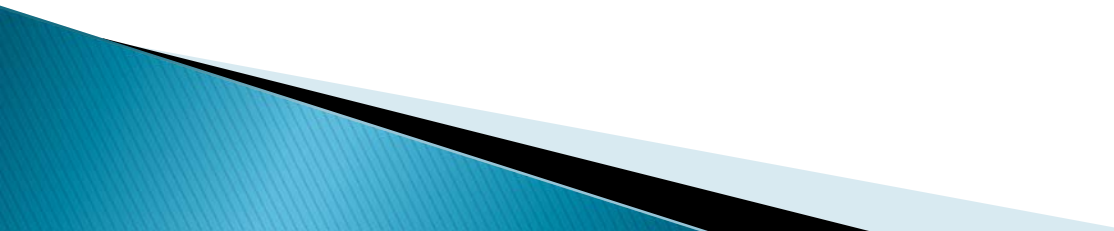
Nada Gligorov, PhD

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.
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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.
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Negative view of microbes

Germ Farm



Scrub'em!

www.1st-in-handwashing.com

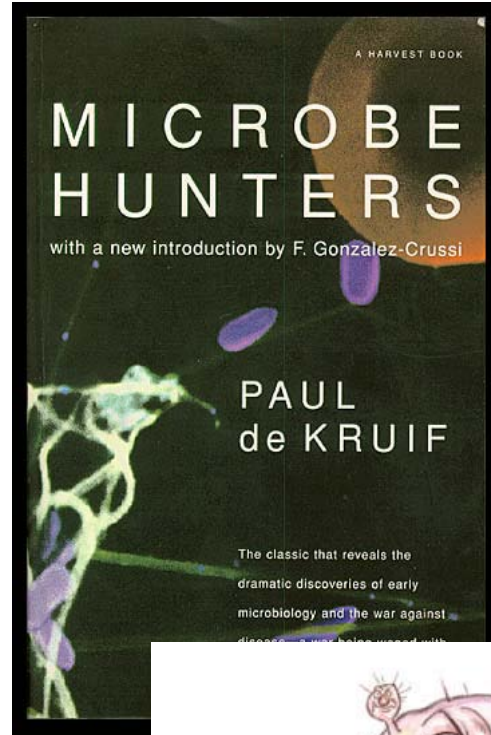


Illustration: Don Smith



PETE MOORE BSc, PhD
**THE NEW KILLER
GERMS**

AVIAN FLU • MRSA • SARS • ANTHRAX • EBOLA
LEGIONNAIRE'S DISEASE • MONKEY POX
NEW-VARIANT CJD



**WHAT YOU NEED TO KNOW ABOUT DEADLY
DISEASES OF THE TWENTY-FIRST CENTURY**

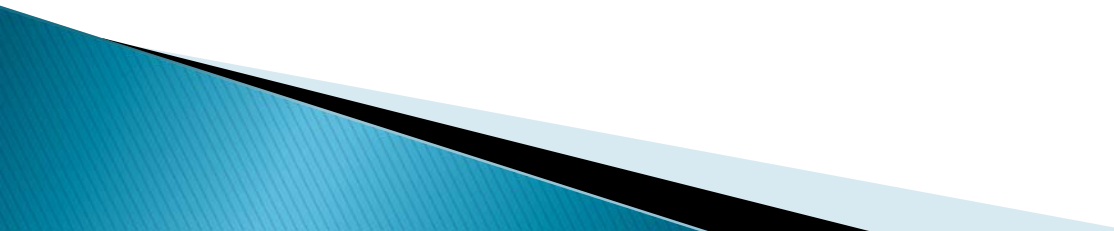


Positive View of Microbes



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.
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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.

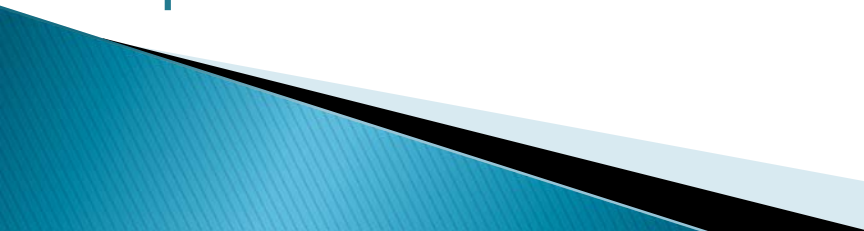


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Key Recommendations:

Privacy

- 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.
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Key Recommendations:

Property:

- 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).



Key Recommendations: Research

- 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

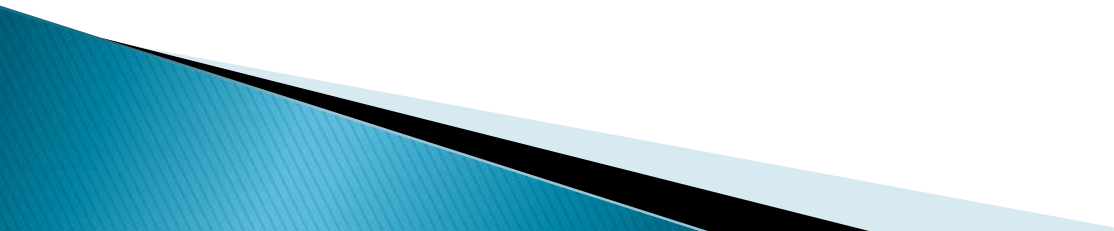


Basic research using microbiome biobanks and sample banks will pose only *de minimis* risk, and knowledge gained from studies will be broadly applicable, hence:

- 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.
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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.

