

The Human Microbiome Project: Ethics from the Trenches

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Laura S. Achenbaum
Sheryl McCurdy
Simon N. Whitney
Melody J. Slashinski
Amy L. McGuire (PI)



THE UNIVERSITY of TEXAS
SCHOOL OF PUBLIC HEALTH



“Ethical, Legal, and Social Dimensions of Human Microbiome Research”

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(PI: Amy L. McGuire)

Considering the ethical, legal and social implications
(**ELSI**) of human microbiome research through an
exploration of the Human Microbiome Project (**HMP**)

The Human Microbiome Project

Overview of HMP Aims

- 1) Develop a reference set of microbial genome sequences to begin characterization of the human microbiome (Jumpstart initiative)
- 2) Examine relationship between disease and changes in microbiome (Demonstration projects)
- 3) Develop new technologies (e.g. for culturing)
- 4) Develop new tools for the computational analysis of data
- 5) Establish a Data Analysis and Coordination Center (DACC)
- 6) Establish a resource repository
- 7) Examine the ELSI of HMP Research

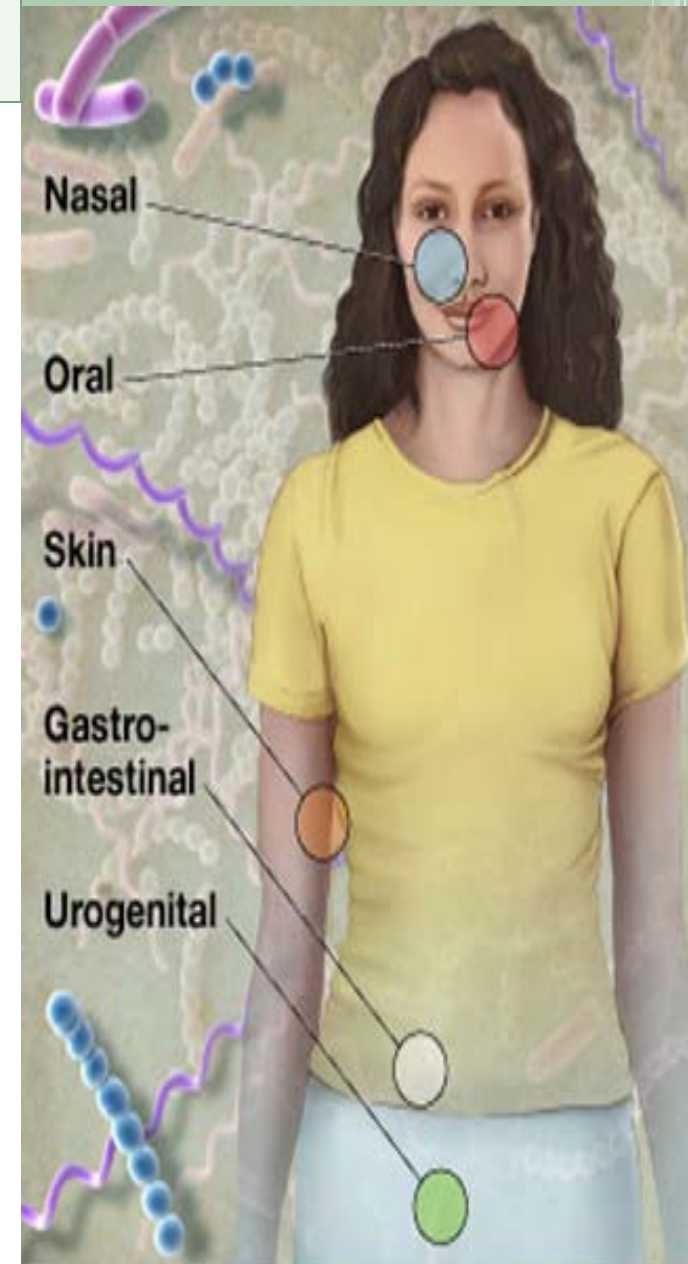


Image source: <http://commonfund.nih.gov/hmp>

Specific Aims

Describe recruits and participants’ ideas about the HMP (and participants’ experiences of the HMP) as it relates to them physically, socially, and culturally and as it relates to their notions of health and disease.

Survey and interview participants recruited into the Jumpstart initiative at Baylor College of Medicine (BCM)

Describe the ethical, legal, and social challenges of conducting the HMP from the perspective of study investigators and project leaders at the NIH.

Interview an array of investigators/project leaders working on HMP

Data Collection

Participants

231 Names received (BCM)



182 Individuals invited



103 Surveys completed

70 Participants

32 Ineligibles

1 Decliner



82 Survey takers agreed to follow-up



50 Complete interviews to date

41 Participants

9 Ineligibles

Investigators

140 Investigators/Project Leaders invited



88 Agreed to participate



60 Complete interviews to date
(with 63 unique individuals)

Highlights from Participant Demographics



	Survey Takers	Interviewees
Age	76% 21-30 years old 23% 31-40 years old	76% 21-30 years old 24% 31-40 years old
Gender	62% Female 38% Male	66% Female 34% Male
Race	60% White 19% Other	70% White 18% Other
Ethnicity	85% Not Hispanic	84% Not Hispanic
Occupation	82% students or in medical/research-related fields	92% students or in medical/research-related fields



**Three Emerging Issues
from Investigator and Participant Interview Data***

**from preliminary analyses of pre-published data*

- Informed Consent
- Inclusion of Participants
- Understandings of Risk

Consent – Understanding

LENGTH AND LANGUAGE

Investigator Perspectives:

Concern that the nature of the consent document hinders the informed consent process

“I cannot remember how long this consent form is, but how much can a person really retain if they have a 15-page consent form? What do they really get out of that?”

Participant Perspectives:

Overall comfort with the consent document

“It was long, but stuff like this is going to be long. You can’t really shorten it, you know, truncating things that you actually need to tell the volunteer.”



Consent – Understanding



PARTICIPANTS' ABILITY TO UNDERSTAND MATERIAL

Investigator Perspectives:

Participants may not be able to understand consent's content

“I think the whole ethical issue about informed consent is how truly informed can an unsophisticated individual be?”

Participant Perspectives:

High levels of understanding, largely because of educational/occupational backgrounds or other research experience

“Well, I’m pretty familiar with medical jargon so, and I’ve written an IRB...so I thought the language was easy to understand. The objectives were easy to understand. What was needed from the patient was easy to understand.”

“...it wasn’t confusing. It may have been confusing for nonmedical personnel.”

Consent as Relationship Tool

CONSENT AND TRUST

Investigator Perspectives:

Consent as a tool for establishing trust

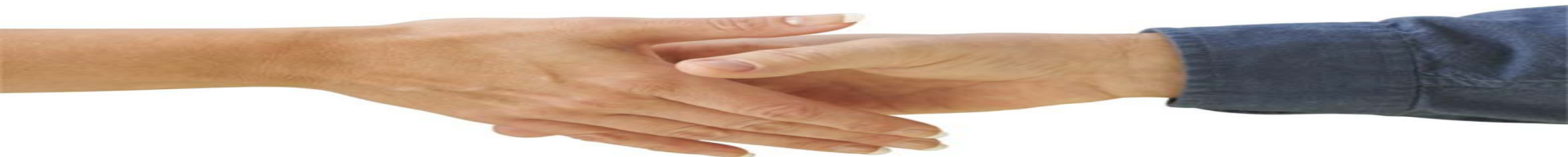
“I mean, fair or not, or whatever...they trust you or they don’t trust you, and that is what drives the consent.”

Participant Perspectives:

Strong developing theme of trust; relates to trust in BCM, the scientists and in NIH-funded research

“For me, part of it made it the fact that it was through Baylor, so I understood that whatever they’re doing is legit, I guess you would say.”

“...it’s like, I trust scientists and I think that the people who are involved are competent...”



Inclusion of Participants

Considering Race and Ethnicity

Investigator Perspectives:

HMP Jumpstart population = **19.3%** minority participants

Concerns:

Diversity across other socio-demographic variables

“...we’re taking very healthy, mostly medical students and graduate students...they’re most likely from relatively privileged backgrounds where they’ve had good nutrition most of their lives and, you know, all the medications and such that they’re supposed to have.”

Data Interpretation

“So I would feel uncomfortable if someone were to take my data that I had publicly released and make statements about race and ethnicity that are simplified arguments based on the limited amount of data that is being publicly released and doesn’t understand that there are multiple other factors that are tracking with race and ethnicity in this small population...”



Inclusion of Participants



Healthy and Normal

Investigator Perspectives:

A logical place to start

“To some extent, again, it’s difficult to know what normal is, and that’s a challenge, but you’ve got to start somewhere...”

Unrealistic standards

“They were too healthy compared to the normal American population. They were not a good sampling. They were healthy, but that healthy was not normal.”

Inclusion of Participants

Participants' Thoughts about Inclusion

-Understand the criteria used; thoughtful of HMP's scientific design

“Well, I understand that it's important to control for a lot of things...I know it's not a pilot project, but it's new, it's exploratory, and you don't know what kind of problems you will run into.”

-Some sensitivities:

“They're the ones kind of declaring whether or not you're the ideal human subject.”



Understandings of Risk

Investigator Perspectives

Risks to Participants

- **Concerns about assurance of privacy and confidentiality**
Uncertainty about identifiability now and in the future

Social Risks

- **Managing Public *Reactions to Science***

The public becoming more aware of bacteria selves could lead to increased use of unregulated or other commercial products whose health claims have not been substantiated by the science

- **Managing Public *Expectations about Science***

Reinforcing the idea that this is exploratory research; concrete applications are years away

“So one needs to be realistic in that translation. One needs to be optimistic and say there’s great hope, but you need to balance that with a realistic assessment of what’s the time frame.”



Understandings of Risk

Participant Perspectives

HMP largely deemed to be a low risk study

Survey results

69% participants and **84% ineligible** participants saw **no** risks associated with HMP

Most Cited Risks:

Physical Risks: *blood draw, skin scrape*

Privacy-Related Risks: *loss of confidentiality, insurance discrimination*



Understandings of Risk

Participant Perspectives

Little Physical Risk

HMP classified as non-invasive = no injections, no diseases contracted

“...I mean, nothing was put into my body. They just looked at stuff that came out.”

Confidence in the Assurance of Privacy

Comfort with measures taken to maintain privacy

“I think that you have enough privacy when they do what they do to dis-identify, to un-identify your information. I don't feel like it would be an issue in this particular study.”

“...you're pretty much just a number.”



Understandings of Risk



Participant Perspectives

Considering risks in light of benefits

“...but overall the risks were very low, and the benefits to the research that could take place and the potential for the societal benefit was a lot higher than any risk to participating.”

Benefits Most Cited:

Compensation

Interest in the project + desire to contribute to the science

Next Steps...

Continued analysis of the ethical, legal and social implications of the HMP and of human microbiome research, in general

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