
* Image taken from the Wired

Bioethics, Social Responsibility, and Community Engagement

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Learning Goals

1. Describe the four principles of bioethics and apply them to case studies

2. Identify shortcomings of the four principle of bioethics

3. Understand the benefits of social responsibility and community-engaged research

What is Bioethics?

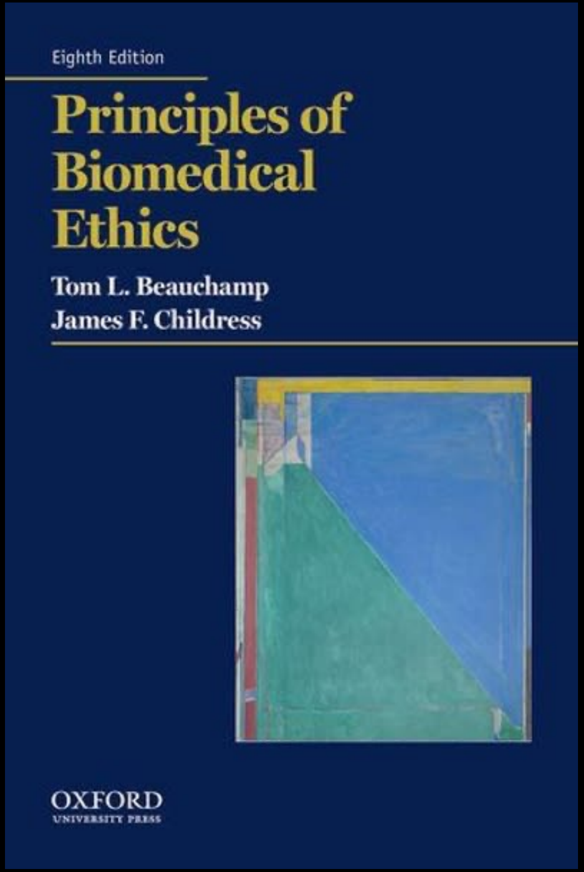
The study of ethical, social, and legal issues that arise in biomedicine and biomedical research. (National Institute of Environmental Health Sciences)

Includes:
- Medical/Clinical ethics
- Research ethics
- Environmental ethics
- Public health ethics

Stanford MEDICINE | Stanford Center for Biomedical Ethics

Four Principles of Bioethics

1. Principle of **respect for autonomy**
2. Principle of **nonmaleficence**
3. Principle of **beneficence**
4. Principle of **justice**



Why does it matter whether our research is ethical?

- Part of the Responsible Conduct of Research (RCR)
- To prevent repeating past research abuses
- To think about potential future applications and identify how we may want to prepare/respond

Pressures from:

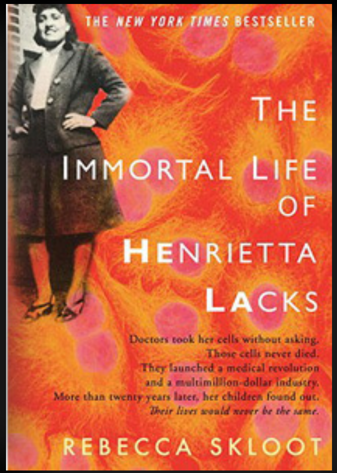
- Institutional Review Board
- Funding agencies
- The public

Catherine Tai, taken from Reuters

How do we decide what makes research ethical?

Examples of Historical Missteps

- Newborn blood spots used in research (without parental consent)
- Cultured cancer cells created “The Immortal Life of Henrietta Lacks”
- Natural progression of untreated syphilis in African American males in Tuskegee
- Nuu-Chah-Nulth tribe (arthritis study used samples for other research)
- Stanford Prison Experiment (study of behavior when treated like prisoners)
- Human Genome Diversity Project (study on human migration and ancestry)
- “Warrior Gene” in Maori people (aggressive behavior with stereotypes)


THE NEW YORK TIMES BESTSELLER

THE IMMORTAL LIFE OF HENRIETTA LACKS

Doctors took her cells without asking.
Those cells never died.
They launched a medical revolution
and a multimillion-dollar industry.
More than twenty years later, her children found out.
Their lives would never be the same.

REBECCA SKLOOT

Slide credit: Nanibaa’ Garrison

What Makes Clinical Research Ethical?

Ezekiel J. Emanuel, MD, PhD; David Wendler, PhD; Christine Grady, PhD

☐ Author Affiliations

JAMA. 2000;283(20):2701-2711. doi:10.1001/jama.283.20.2701

Table 1. Selected Guidelines on the Ethics of Biomedical Research With Human Subjects*

Guideline	Source	Year and Revisions
	Fundamental	
Nuremberg Code[35]	Nuremberg Military Tribunal decision in *United States v Brandt*	1947
Declaration of Helsinki[36]	World Medical Association	1964, 1975, 1983, 1989, 1996
Belmont Report[37]	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	1979
International Ethical Guidelines for Biomedical Research Involving Human Subjects[38]	Council for International Organizations of Medical Sciences in collaboration with World Health Organization	Proposed in 1982; revised, 1993
	Other	
45 CFR 46, Common Rule[8]	US Department of Health and Human Services (DHHS) and other US federal agencies	DHHS guidelines in 1981; Common Rule, 1991
Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products[42]	World Health Organization	1995
Good Clinical Practice: Consolidated Guidance[44]	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use	1996
Convention on Human Rights and Biomedicine[43]	Council of Europe	1997
Guidelines and Recommendations for European Ethics Committees[45]	European Forum for Good Clinical Practice	1997
Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials[46]	Medical Research Council, United Kingdom	1998
Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda[47]	Uganda National Council for Science and Technology	1998
Ethical Conduct for Research Involving Humans[48]	Tri-Council Working Group, Canada	1998
National Statement on Ethical Conduct in Research Involving Humans[49]	National Health and Medical Research Council, Australia	1999

*CFR indicates Code of Federal Regulations. More extensive lists of international guidelines on human subjects research can be found in Brody[39] and Fluss.[40] An extensive summary of US guidelines can be found in Sugarman et al.[41]

THE BELMONT REPORT

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979

Basic Ethical Principles

- Respect for Persons
- Beneficence
- Justice

Autonomy & Respect for Persons

Autonomy:

- Rational agents are involved in making informed and voluntary decisions.
- The basis for the practice of "informed consent"

Respect for Persons:

- “Individuals should be treated as autonomous agents”
- “Persons with diminished autonomy are entitled to protection”
- Respecting persons means respecting their rights and welfare (e.g., by maintaining confidentiality)

(Belmont Report)

Beneficence & Non-Maleficence

Beneficence

- Maximize possible benefits and minimize possible harms

Non-Maleficence

- Do not harm

Justice

“Who ought to receive the benefits of research and bear its burdens?”
(Belmont Report)

Ways to distribute burdens and benefits:
- to each person an equal share
- to each person according to individual need
- to each person according to individual effort
- to each person according to societal contribution
- to each person according to merit

Broadly: Giving each person their due

Who gets to decide what makes research ethical?

Researchers are regulated by policies such as the Common Rule (45 CFR 46), research ethics committees, and Institutional Review Boards (IRBs).

* Image taken from NYT , Benjamin Currie

The Problem:

Existing mechanisms for regulating the ethical conduct of research are limited in their ability to appraise the downstream implications of research, especially the potential social harms.

IRBs are *expressly prohibited* by the Common Rule from considering any broad social or policy risks.

* Image taken from NYT , Benjamin Currie

- IRBs generally don’t regulate risks other than those directly encountered by research participants.
- Per the Common Rule, IRBs are allowed to judge the broader social benefits of research; that is, whether research has the potential to enhance health or knowledge.

* Image taken from NYT , Benjamin Currie

“I think it is human nature to see the good in everything though often on a subconscious level. We look at situations, products, financial offers and a million other things and think to ourselves how this can immediately better our lives. **What is difficult, and usually through hindsight, are the potential downsides to these same things**…Unintended negative consequences can then often occur…”

– Wrestling with Social and Behavioral Genomics
Community Sounding Board Member

Researchers have an obligation to address the social implications of their work in an ethically responsible manner. This includes:

- Obligation to do no harm
- Obligation to help others
- Obligation to society as they have benefitted, directly or indirectly, from government support of their education and research
- Obligation to help the public address the implications of research

(Resnik and Elliott, 2016)

Social Responsibility

The role of social responsibilities in the ethical conduct and translation of scientific research are poorly understood.

* Image taken from NYT , Benjamin Currie


AAAS
AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

The Social Responsibilities of Scientists and Engineers: A Global Survey

- Researchers view themselves as having social responsibilities
- Their beliefs about their social responsibilities do not translate into consistent behaviors or actions.

Social Responsibility

1. **Dilemmas related to problem selection:** deciding whether proposed research is worthwhile to do, to fund, etc.

2. **Dilemmas related to publication and data sharing:** deciding whether to publish a study, where to publish, and how to publish it

3. **Dilemmas related to engaging society:** deciding whether or how to engage the public

(Resnik and Elliott, 2016)

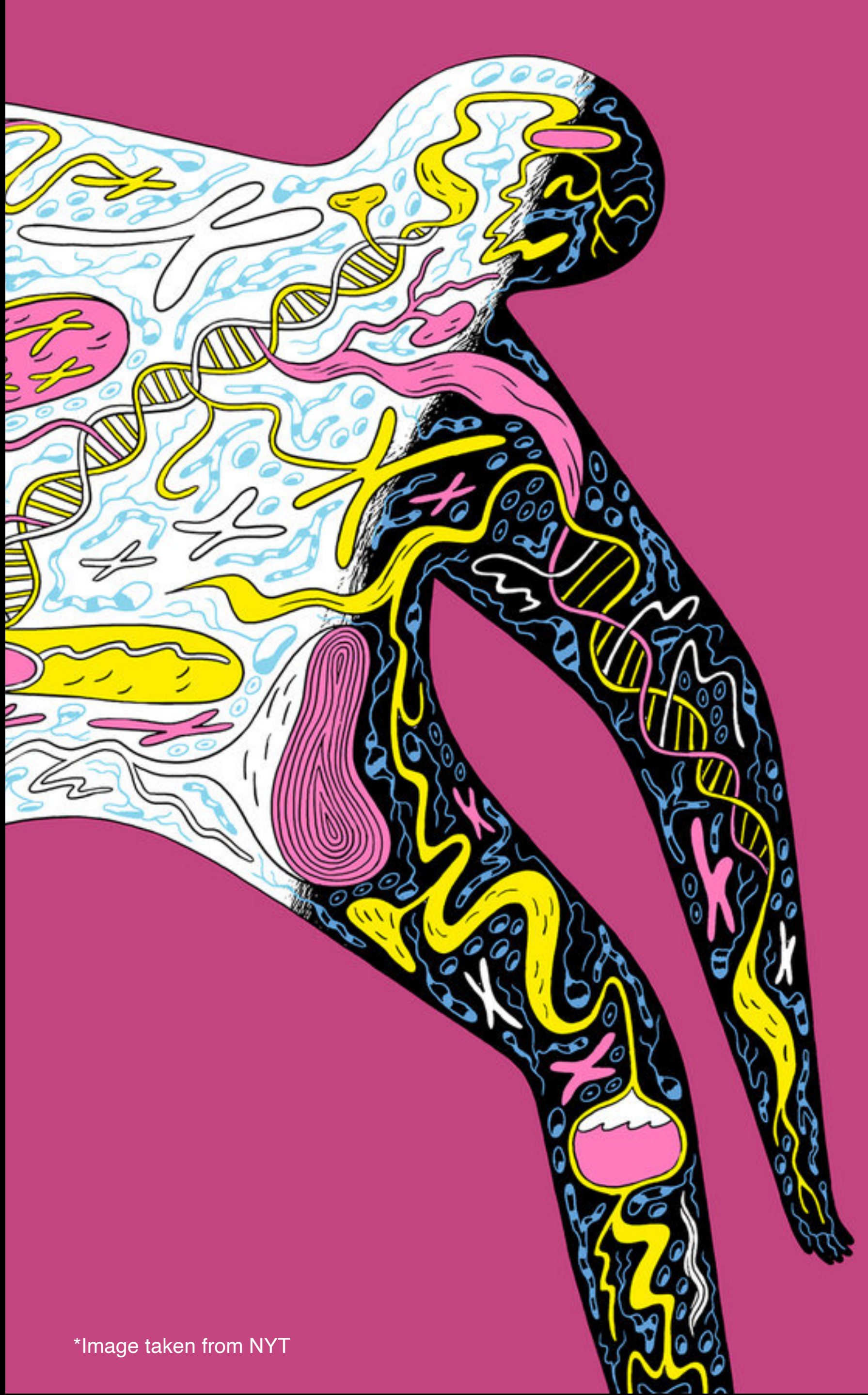


*Image taken from NYT

There is heightened social responsibility for genomic researchers.

Genes are sources of

“promise and peril”

(Bliss, 2018)

* Image taken from NYT , Benjamin Currie

Genes are objects of

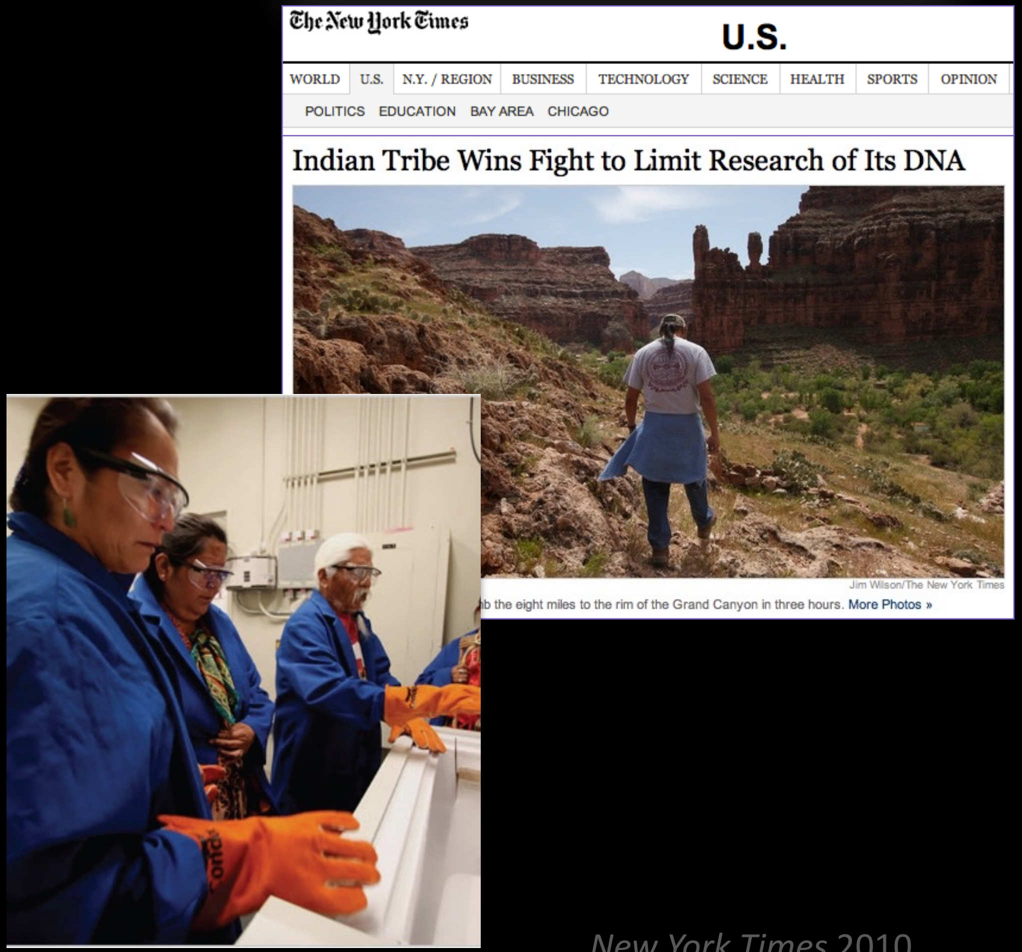
“fear and fascination”

(Harden, 2021)

* Image taken from NYT , Benjamin Currie

Havasupai Tribe’s experience

- Original goal: a genetic study of diabetes
- An informed consent process was conducted for studies on “behavioral / medical problems”
- Blood samples collected from ~400 tribal members
- Samples were shared with other researchers; used in studies on schizophrenia, inbreeding, and migration
- Tribe sued over misuse of DNA samples
- No legal precedent after the out-of-court settlement
    - Technicalities (timing of lawsuit, informed consent form, etc.)
    - DNA samples were returned to Havasupai



The New York Times

U.S.

WORLD | U.S. | N.Y. / REGION | BUSINESS | TECHNOLOGY | SCIENCE | HEALTH | SPORTS | OPINION

POLITICS EDUCATION BAY AREA CHICAGO

Indian Tribe Wins Fight to Limit Research of Its DNA

Jim Wilson/The New York Times

b the eight miles to the rim of the Grand Canyon in three hours. More Photos »

Slide credit: Nanibaa’ Garrison

New York Times 2010

Nuu-Chah-Nulth Tribe’s experience

- Donated 800 samples to a rheumatoid arthritis study in the 1980’s (U British Columbia)
- Investigator took samples with him to U Utah, U Oxford (UK)
- Studies conducted on ancestry, retroviruses, and drug abuse
- Published >200 papers throughout his career, never reported results to tribe


Ha-Shilth-Sa

Canada’s Oldest First Nations Newspaper - Serving Nuu-chah-nulth-aht since 1974

Vol. 31 - No. 25 - December 16, 2004 haašiťsa “*Interesting News*”

Canadian Publications Mail Product
Sales Agreement No. 40047776

Nuu-chah-nulth blood returns to west coast

By *David Wiwchar*
Ha-Shilth-Sa Reporter

Ahousaht - After a 20-year journey halfway around the world, hundreds of vials of Nuu-chah-nulth blood have returned home to the west coast. And although people welcome its return, many remain critical of the system that allowed its misuse in the first place.

After a 20-year journey halfway around the world, hundreds of vials of Nuu-chah-nulth blood have returned home to the west coast. And although many people welcome its return, many remain critical of the system that allowed its misuse in the first place.

Dr. Richard (Ryk) Ward took 883 vials of blood between 1982 and 1985 under the guise of a $330,000 Health Canada funded study of arthritis amongst Nuu-

out the study, I would like to survey every person in Ahousaht so that we can be sure exactly who has a problem with rheumatic disease and who heeds help.”

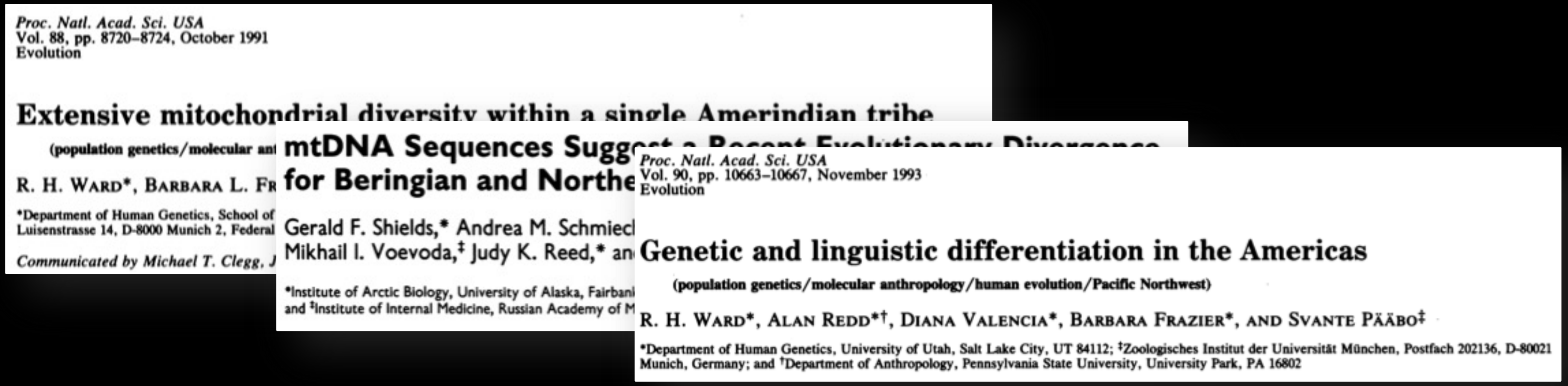
According to Ward’s final report, published in 1987, his team of researchers interviewed 1,878 (82%) of all 2,300 adult Nuu-chah-nulth, in 13 different reserve communities and members living away from home in Port Alberni, Tofino, Nanaimo, and Victoria. Of those surveyed, 883 people (44.3%) were selected to give 30 ml of blood so research could begin on whether there was a genetically inherited aspect to rheumatic diseases.

“In Caucasian populations the overall prevalence is of the order of 1%,” Ward described in his project overview. “The prevalence rates for rheumatoid arthritis in adult Native Indians are between 3% and 8%,” he wrote.

But after he failed to find any genetic markers in the DNA, he shelved the study, and that’s where things started to go wrong.

In 1986, Ward left his position as

“Our family has been hit pretty hard by arthritis,” said Ahousaht Elder Cosmos Frank. “It’s really, really hard to watch someone you love suffer like that when you can’t do anything to help. It’s hell”.


Proc. Natl. Acad. Sci. USA
Vol. 88, pp. 8720–8724, October 1991
Evolution

Extensive mitochondrial diversity within a single Amerindian tribe

(population genetics/molecular an

R. H. Ward*, Barbara L. Fr

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Communicated by Michael T. Clegg, J

mtDNA Sequences Sugg
for Beringian and Northe

Gerald F. Shields,* Andrea M. Schmiec
Mikhail I. Voevoda,‡ Judy K. Reed,* an

*Institute of Arctic Biology, University of Alaska, Fairban
and ‡Institute of Internal Medicine, Russian Academy of M

Proc. Natl. Acad. Sci. USA
Vol. 90, pp. 10663–10667, November 1993
Evolution

Genetic and linguistic differentiation in the Americas

(population genetics/molecular anthropology/human evolution/Pacific Northwest)

R. H. Ward*, Alan Redd*†, Diana Valencia*, Barbara Frazier*, and Svante Pääbo‡

*Department of Human Genetics, University of Utah, Salt Lake City, UT 84112; ‡Zoologisches Institut der Universität München, Postfach 202136, D-80021 Munich, Germany; and †Department of Anthropology, Pennsylvania State University, University Park, PA 16802

Slide credit: Nanibaa’ Garrison

Dilemmas in practicing social responsibility

1. **Problem selection**

2. Publication and data sharing

3. Engaging society

(Resnik and Elliott, 2016)

*Image taken from NYT

Risk

Benefit

Catherine Tai, taken from Reuters

Dilemmas in practicing social responsibility

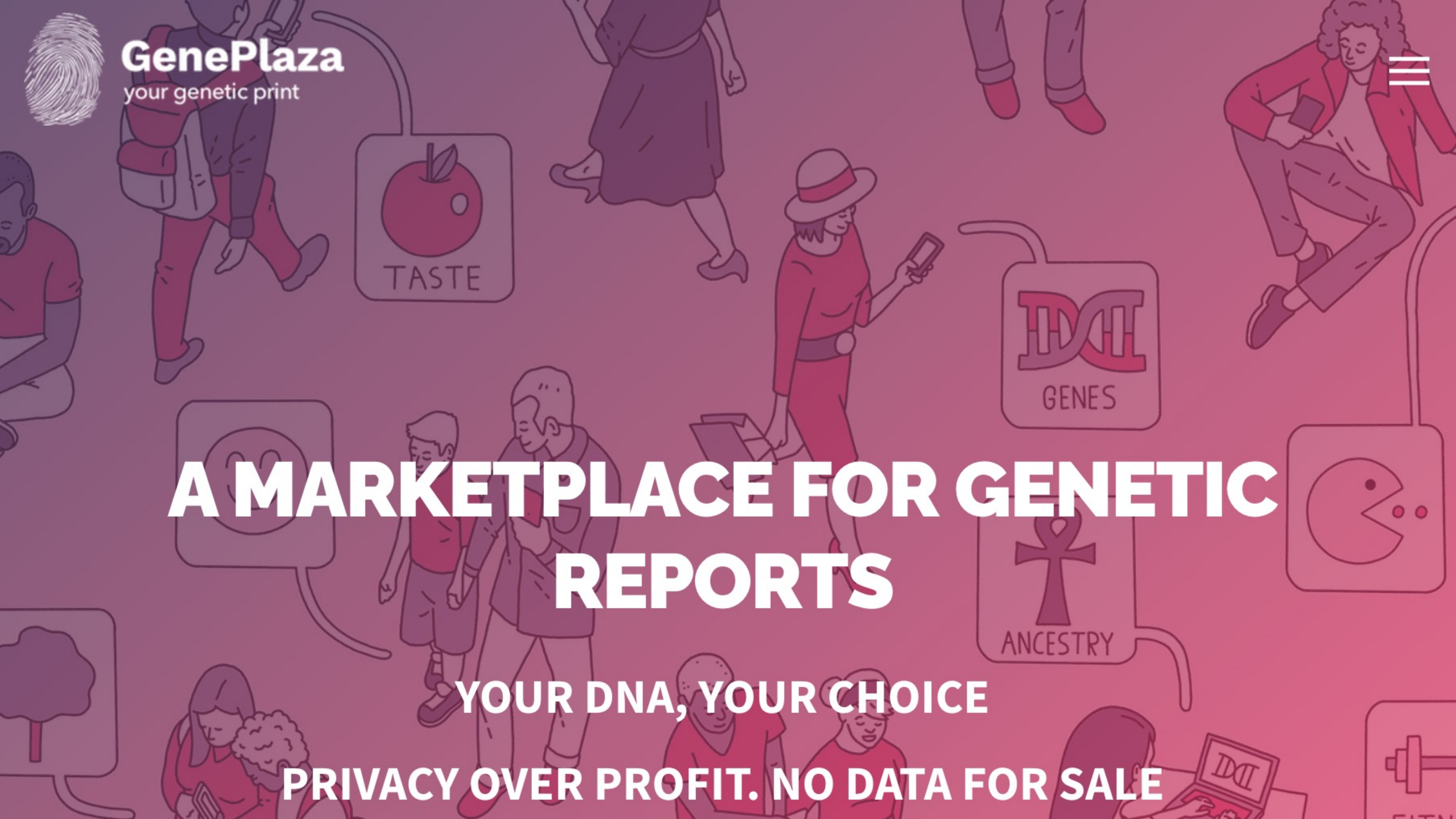
1. Problem selection

2. **Publication and data sharing**

3. Engaging society

(Resnik and Elliott, 2016, p. 1)

*Image taken from NYT



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Complete your **DNA Romance profile** and wait for us to predict your compatibility scores.

Read more

Your Matches

Within **just 2 minutes** you will see your matches!

Read more

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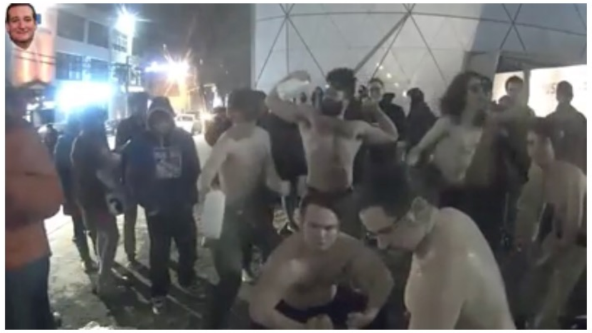
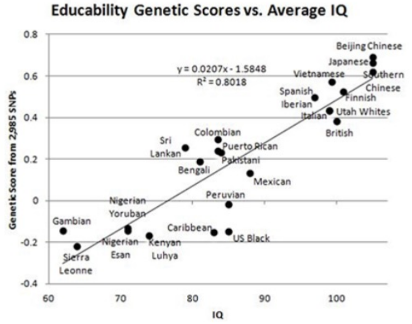
Why White Supremacists Are Chugging Milk (and Why Geneticists Are Alarmed)

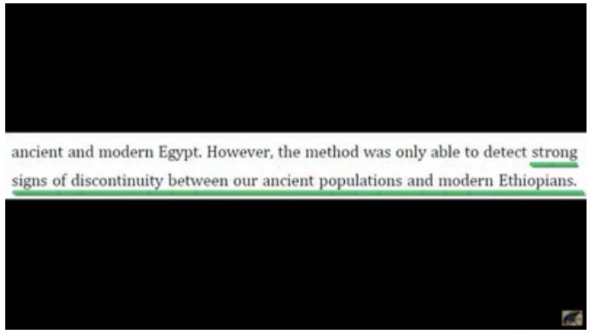
Give this article

400



Educability Genetic Scores vs. Average IQ





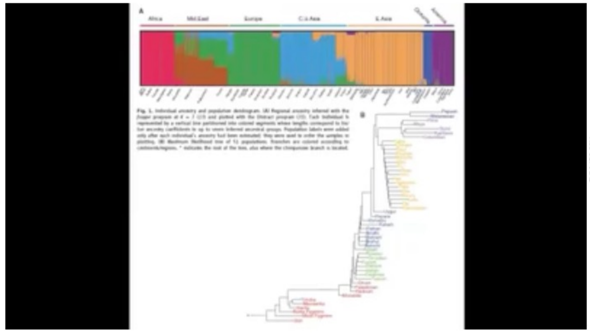
ancient and modern Egypt. However, the method was only able to detect strong signs of discontinuity between our ancient populations and modern Ethiopians.

The Cultural Marxist War against Darwinism

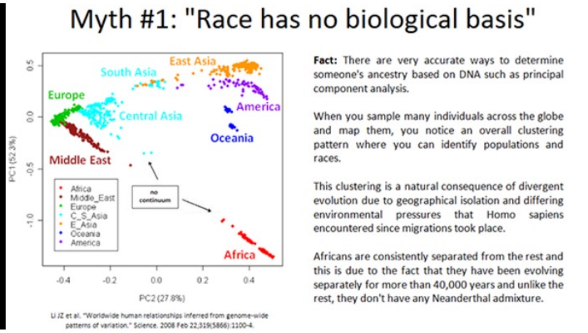
Creationists: evolution is a social construct, not biologically real.
Liberal Creationists: race is a social construct, not biologically real.
Charles Darwin: I'm not a creationist; I actually wrote: "There is, however, no doubt that various races, when carefully compared and measured, differ much from each other...."

"Race is a social construct"
LOL
Does anyone believe this nonsense?

The truth: Race is biologically real.



Myth #1: "Race has no biological basis"



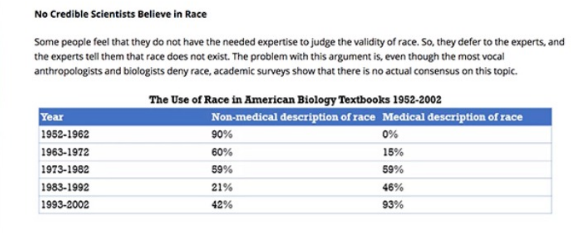
Li JZ et al. "Worldwide human relationships inferred from genome-wide patterns of variation." Science. 2008 Feb 22;319(5866):1100-4.

Fact: There are very accurate ways to determine someone's ancestry based on DNA such as principal component analysis.

When you sample many individuals across the globe and map them, you notice an overall clustering pattern where you can identify populations and races.

This clustering is a natural consequence of divergent evolution due to geographical isolation and differing environmental pressures that Homo sapiens encountered since migrations took place.

Africans are consistently separated from the rest and this is due to the fact that they have been evolving separately for more than 40,000 years and unlike the rest, they don't have any Neanderthal admixture.



No Credible Scientists Believe in Race

Some people feel that they do not have the needed expertise to judge the validity of race. So, they defer to the experts, and the experts tell them that race does not exist. The problem with this argument is, even though the most vocal anthropologists and biologists deny race, academic surveys show that there is no actual consensus on this topic.

The Use of Race in American Biology Textbooks 1952-2002

Year	Non-medical description of race	Medical description of race
1952-1962	90%	0%
1963-1972	60%	15%
1973-1982	59%	59%
1983-1992	21%	46%
1993-2002	42%	93%

Lothrop Stoddard World Race Map (1920):

New York Times, October 2018

Dilemmas in practicing social responsibility

1. Problem selection
2. Publication and data sharing
3. **Engaging society**

(Resnik and Elliott, 2016, p. 1)

*Image taken from NYT

BioSocieties
https://doi.org/10.1057/s41292-021-00239-3

ORIGINAL ARTICLE

“The elephant in the room”: social responsibility in the production of sociogenomics research

Daphne Oluwaseun Martschenko[1,2]

“We knew that this is extremely sensitive material from the very early days…we had dozens if not hundreds of really serious conversations about this…We basically decided that we wanted to take a proactive approach… the journalists want headlines that are breathtaking or sensational or, ‘gene for x has been found’. **We spent a lot of time talking to journalists** trying to convince them that they shouldn’t write such a paper or such a story and usually we considered it a success when after talking to us for an hour they decided not to write about it.”

– SBG Researcher

What is community engaged research?

Community engagement (non research)	UCSF presence at community events Listening sessions, town halls etc to learn about community needs and preferences
Low engagement	Focus groups or random surveys – talking to subset of people about a specific project
Moderate engagement	Partnering with a community organization to assist in implementation (recruitment, lab work, etc)
High engagement	Community advisory board – community offers feedback on various study processes
Highest engagement	Community Based Participatory Research – Community and researcher act in partnership to jointly explore a problem

Slide credit: Jen James

Why do community engaged research?

Identify	New intersections through understanding how policy and power operate in the real world
Develop	culturally relevant and useful interventions
Disseminate	Findings and interventions
Reach	key populations

Slide credit: Jen James

Who is community?

A group of people linked by social ties who share common perspectives or interests, and may also share a geographic location (MacQueen et al.)

So, community could be:

- Residents of San Francisco
- Vietnamese Immigrants
- Oncologists
- Billionaires

Community as coded language

Slide credit: Jen James

Non-transactional relationships

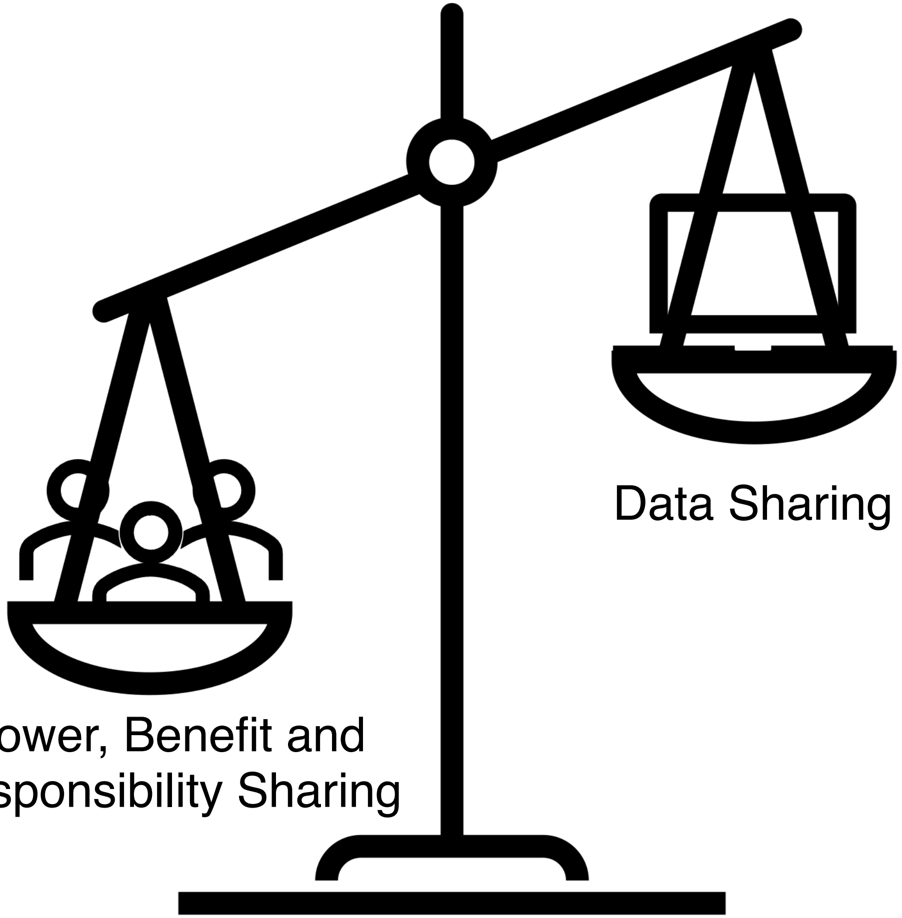
Show up without asking for anything in return

Be up front about research, but don't push research agenda

Building relationships with people who will NOT be research participants

This. Takes. Time.

Slide credit: Jen James



Data Sharing

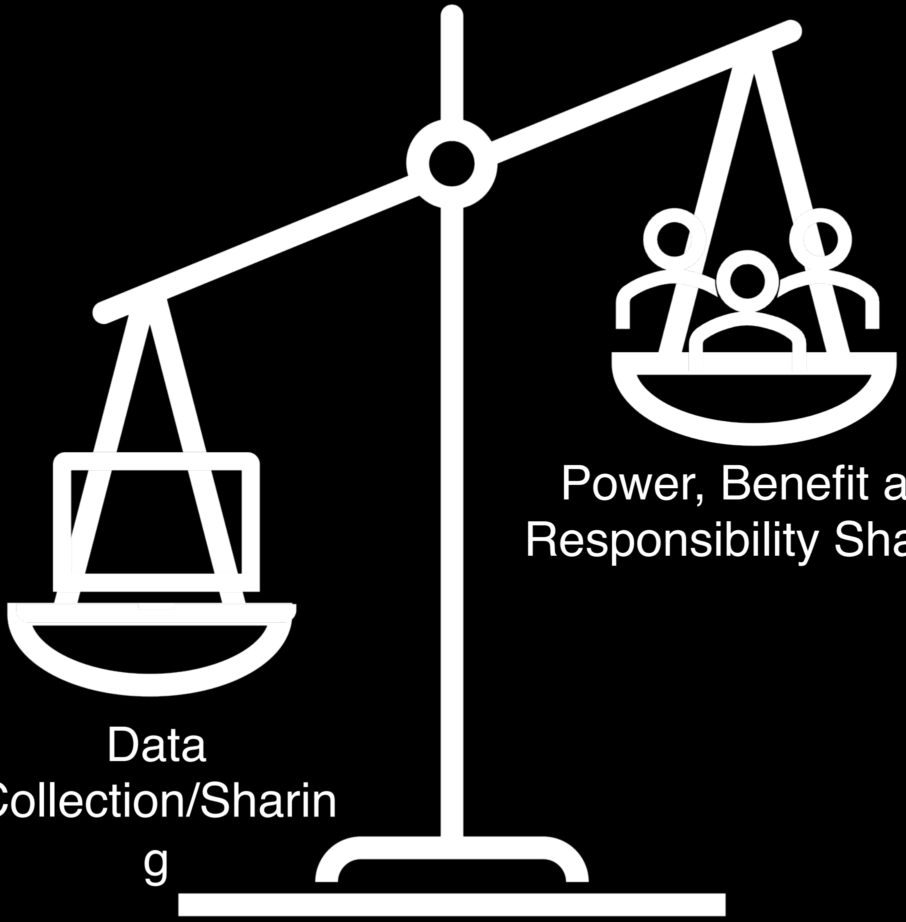
Power, Benefit and Responsibility Sharing

The Problem: Shallow Engagement

- Researchers/clinicians make assumptions up front about communities and then use engagement as way to validate those assumptions
- Communities are brought in after research has already been conceptualized or even conducted
- Communities are asked to comment on already prepared materials rather than involved in the creation of those materials

= a lack of power-sharing between communities and researchers

Shallow Engagement



Power, Benefit and Responsibility Sharing

Data Collection/Sharing

Priorities

Reciprocal Relationships and True Partnership: Requires true power sharing built on mutual respect and benefit

Co-learning: Acknowledges the importance of everyone's contributions and individual expertise

Transparent and Shared Decision-Making Heightens accountability of researchers and demonstrates impact of community engagement

Key Takeaways

Existing Regulations

- Mostly been developed in reaction rather than proactively
- Done little to encourage/enhance social responsibility

IRBs

- IRBs are not the be-all-end-all; will not guarantee the risks outweigh potential benefits.
  - Why? IRBs do not consider broad social and policy implications of research. Some consider group harms, but in specific instances (e.g., harms to indigenous tribal communities)

Key Takeaways: Downstream Implications

- There are few incentives or policies that exist for us to consider the downstream implications of research
  - The downstream implications can be difficult to identify, but failure to try to will stymie efforts to mitigate potential harms and promote potential benefits

- Potential value in broadening who is included in conversations about the risks and benefits of research early in the process
  - Scientists are not the only relevant stakeholder group when it comes to harms and benefits
  - Community engagement is an important way to do this

- When conceptualizing your research, consider the downstream implications (social harms and benefits)

Key Takeaways: Social Responsibility

There are few incentives or policies that exist for us (**all of us**) to consider the role of social responsibility in the ethical conduct/translation of research

- Social responsibilities are difficult to define and exercise, but we all have them
- Researchers are not the only ones with social responsibilities or the only ones who should be thinking about how to exercise them

Social responsibility should be modeled earlier in training

- Cannot be something that just becomes a grant requirement in the future

Given genetics ugly history it is especially important to think of the downstream implications (i.e., broad social harms and benefits) of research

Thank you!

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