


# ETHICS AND RESEARCH

DEPARTMENT OF SCIENCE AND TECHNOLOGY
PHILIPPINE COUNCIL FOR HEALTH RESEARCH AND DEVELOPMENT
**PHILIPPINE HEALTH RESEARCH ETHICS BOARD**

# INTRODUCTION

"How much freedom can scientists exercise in the pursuit of knowledge for society's benefit if they expose human participants to research harm/risks?"

# OBJECTIVES

- More aware of ethical dimensions of research
- Appreciate importance of ethics in research
- Accept that pursuit of societal good and respect for research participants are essential for ethical research
- Ready to initiate dialogue with plural diverse stakeholders regarding ethical issues
- Enthusiastic to integrate ethical dimensions to research implementation and translation –

  "bench to bedside"

# OUTLINE

- Definitions
- PHREB Responsibilities
- Elements of Research Ethics
- Responsible Conduct of Research
- Artificial Intelligence in Health-Related Research: Ethical Issues
- Summary

# DEFINITIONS

## RESEARCH

- An activity that inquires into individual/ community participants
- using **scientific methods**, observation, inference and analysis
- with the aim to develop or contribute to **generalizable knowledge** (including theories, principles and relationships) or any accumulation of information.

# DEFINITIONS

## HEALTH RESEARCH WITH HUMAN BEINGS

1. Social science, biomedical or epidemiologic study in which **human beings are exposed** to manipulation, intervention, observation or other interaction with investigators either directly, or
2. through **alteration of their environment**, or

# DEFINITIONS

## HEALTH RESEARCH WITH HUMAN BEINGS

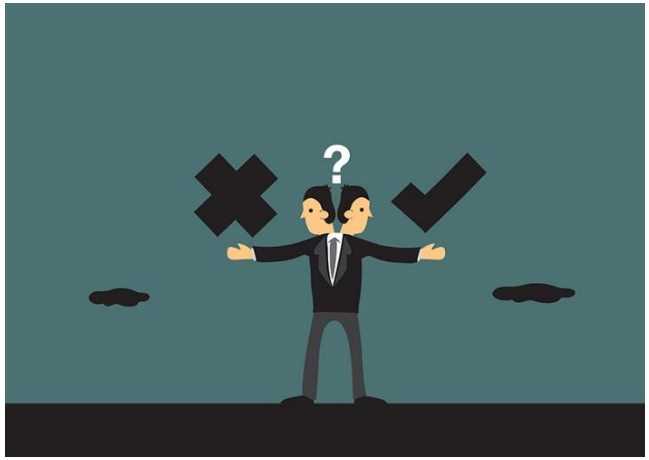
3. Become **individually identifiable** through
   a) use of biological material or
   b) medical or other records. (WHO 2009)

# DEFINITIONS

## ETHICS

- Justification and practice of what is morally good (long / healthy life?) and bad (pain / sickness)
- Justification – theory, principles, human rights, social-cultural values
- Concerned about the nature of ultimate human value (also valuable life) and the standards by which human actions can be judged right or wrong

# DEFINITIONS



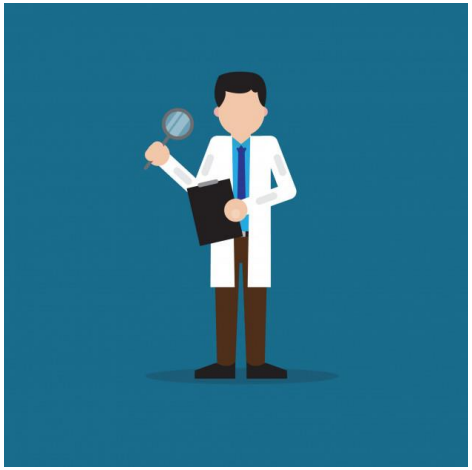

## ETHICS IN RESEARCH

– Framework applying acceptable **ethical justifications for the:**

- protection of human participants
- **responsible conduct** of research and
- application of **research outcomes**

# DEFINITIONS

- **RESEARCHER**
  - A qualified scientist who undertakes **responsibility for the scientific and ethical integrity** of a study from conception to publication
- **PRINCIPAL INVESTIGATOR**
  - Researcher primarily responsible either in general or at a particular center (Site PI)



# DEFINITIONS

## RESEARCH PARTICIPANT

- The person from whom data is collected during observation, interview, manipulation, or other interaction with the investigator

# DEFINITIONS

## PROTOCOL

- A **document** that provides the background, methodology, rationale, and objectives of a study and
- describes its design, organization including ethical and statistical considerations
- (submitted for technical and ethics approval)

# PHREB RESPONSIBILITIES

- ✓ National policy making on health research ethics.
- ✓ Formulation of Guidelines for ethical conduct (2017 National Ethical Guidelines for Health Research).
- ✓ Research Ethics Committees (RECs)
  - ✓ Capacity development: Committee of Information Dissemination, Training and Advocacy
  - ✓ Registration, Accreditation, and Monitoring: Committee on Standards and Accreditation
- ✓ Establishment and Monitoring of national data base: Philippine Health Research Portal
- ✓ Advising on ethical issues in human research

# PROMOTING
# ETHICS IN RESEARCH

- PHREB National Ethical Guidelines (2017)
- Common Rule US Federal policy for protection of human subjects (amended 2018)
- Helsinki Declaration – World Medical Association (2013)
- CIOMS International Ethics Guidelines for Biomedical Research involving human participants (1982, 2002, 2016)
- ICH Harmonized Tripartite guidelines for Good Clinical Practice (1996)
- WHO Standards and Operational Guidance for Ethics Review of Health related Research with human participants (2011)

# Elements of
# RESEARCH ETHICS

1. **Social value**: Improve people's health and well-being.
2. **Informed consent**: Free and informed involvement of participants in decision-making
3. **Vulnerability of participants**: Protection for those with potentially diminished capabilities

# SUBJECTS HAVE BEEN HARMED

- **The significance of Jenner's Cowpox experiment for today's vaccine research**
  - No prior research on animals
  - Exploitation of 8 yr old
  - Compromised capacity to consent
  - "Human challenge" design
- **Saved millions of lives!**

Louis Pasteur watches a rabies vaccination

# Humans developing cow heads: cartoon mocking Jenner

# Elements of
# RESEARCH ETHICS

4. **Risks, benefits and safety**: careful assessment of risks, burdens and benefits
5. **Privacy and confidentiality of information**: observing transparency, legitimate purpose, and proportionality in the use of information
6. **Justice**: Equitable distribution of risks and benefits; just compensation for harm

# Elements of
# RESEARCH ETHICS

4. **Transparency:** Openness about aspects of study that may affect participants, or their decision to give or withhold consent

# RESPONSIBLE CONDUCT OF RESEARCH: Integrity Issues

1. **Scientific competence**
   a) Unqualified researcher
   b) Defective methodology (eg statistically flawed)
2. **Conflict of interest**
   a) Financial interest
   b) Academic or other secondary interest
3. **Data manipulation**
   a) Fabrication
   b) Falsification

AAAS Become a Member

Science

conferences.

# A scientist's fraudulent studies put patients at risk

By Adam Marcus, Retraction Watch

It is also very costly!

# SCIENTIFIC FAKE NEWS MISLEADS SCIENTISTS!

- Primary Prevention of Cardiovascular Disease with a Mediterranean Diet. N Engl J Med April 4, 2013

2150 Citations!

Conclusion

- Mediterranean diet, plus extra-virgin olive oil or nuts, results in substantial reduction in the risk of major cardiovascular events

Retracted after 5 years

# SCIENTIFIC FAKE NEWS MISLEADS SCIENTISTS!

- Cardiac stem cells in patients with ischaemic cardiomyopathy (SCIPIO): initial results of a randomised phase 1 trial. LANCET, NOV 2011

Conclusion

- Infusion of Cardiac Stem Cells led to increased heart function, improved quality of life, and reduced LV scar size

- 906 Citations!

Retracted after 8 years

# TOP 10 RETRACTED AUTHORS

| | |
|---|---|
| **Yoshitaka Fujii**, Japan | 169 |
| **Joachim Boldt**, Germany | 96 |
| **Diederik Stapel**, Netherlands | 58 |
| **Chen-yuan Peter Chen**, Taiwan | 43 |
| **Yoshihiro Sato**, Japan | 43 |
| **Hua Zhong**, China | 41 |
| **Shigeaki Kato**, Japan | 39 |
| **James Hunton**, United States | 36 |
| **Hyung-in Moon**, South Korea | 35 |
| **Jan Hendrik Schön**, United States | 32 |

We don't want Filipino authors on this list!

# Spectre of AI in Social Media

- Unlike humans, bots never tire working 24/7 and can generate huge amounts of content quickly
- Shared and re-tweeted, malicious messages go viral, true or not, and are virtually unstoppable.

# Ethics of AI: Spreading Fake News

- Cyber bots spread false information, amplifying messages
- Criminals and trolls use use fake news to cause harm or to disrupt legitimate organizational operations
- Malicious actors traumatically alter public opinion

# What is Artificial Intelligence?

Theory and development of computer systems able to:

- Perform tasks usually involving human intelligence

  (visual perception, face and speech recognition, decision-making, and language translation)
- Creating algorithms to classify, analyze, and draw predictions from data
- Act on data, learn from new data, and improve over time.

# AI general issues

As machines become more intelligent:

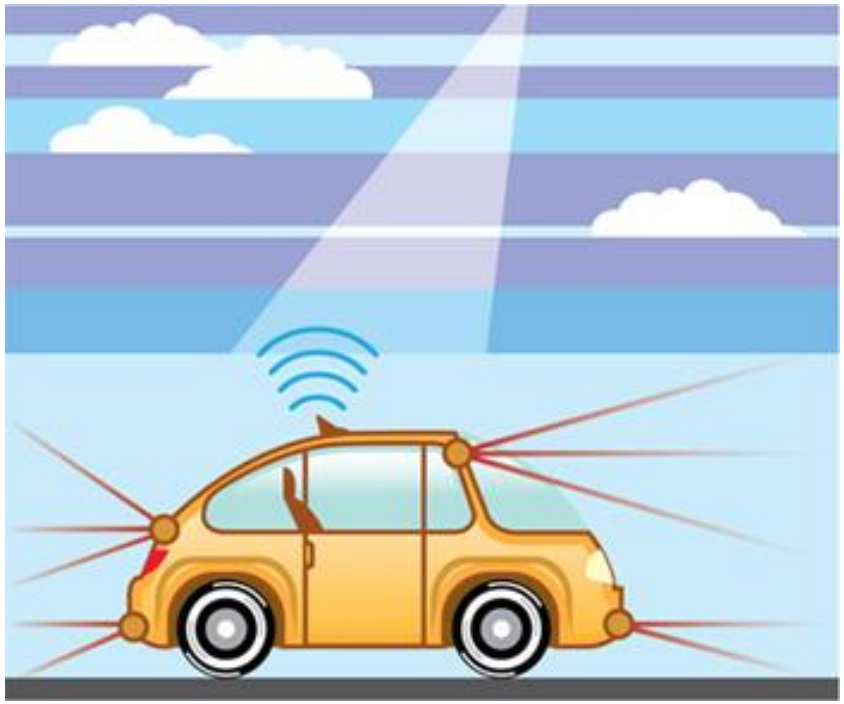
- How should they be treated and viewed in society?
- How should they be governed?
- Should we consider machines as humans, animals, or inanimate objects?
- To what level do we ascribe liability and responsibility for harm (eg a self-driven car hitting a pedestrian)
- What aspects of AI research are human participant research?

# Autonomous car

- "Driverless" - Capable of moving with little or no human involvement.
- Can sense and understand its environment
- Able to move safely
- Uses sensors to capture huge amount of data
- Data is processed by the vehicle's autonomous driving computer system
- Algorithms programmed to "ENSURE ETHICAL MOVEMENT"

# Autonomous car: ethical issues

- What aspects of research on autonomous cars involve human participant research?
- Who should be ethically responsible for accident harms?



Bob Ward, Self-Driving Cars: Pros and Cons, and Unknowables https://yaleclimateconnections.org/2016/04/electric-cars-pros-cons-and-unknowables/

# AI in wearable healthcare technology

- Smartwatches to analyze data to alert users and healthcare providers on potential health issues/ risks
- Eases consult work of professionals/ patients and prevents unnecessary hospital visits
- At what price?
  - Privacy intrusions
  - Unauthorized use of data (hacking)
  - Accuracy/ ethical errors due to algorithm bias

# Contact tracing app in South Korea

- Tracks location of new airport arrivals
  - Use government smartphone app that tracks their location and asks them to report any symptoms
  - Follow up to ensure asymptomatic are tested within three days
- Mandatory location tracking bracelets for people who break quarantine laws
- Health authorities use CCTV footage, credit card transaction data, travel information, and location data to keep tabs on patients

# Contact tracing app in South Korea

- Health authorities use:
  - card transaction data,
  - travel information,
  - location data
- to monitor patient movement

- Public database with:
  - extraordinarily detailed information
  - every infected individual
  - exact movements around the country

# Issues with AI: Contact tracing app

- Privacy
- Subsequent use of data
- Social acceptability
- Assessment of actual effectiveness and benefits

# Machine Bias

## There's software used across the country to predict future criminals. And it's biased against blacks.

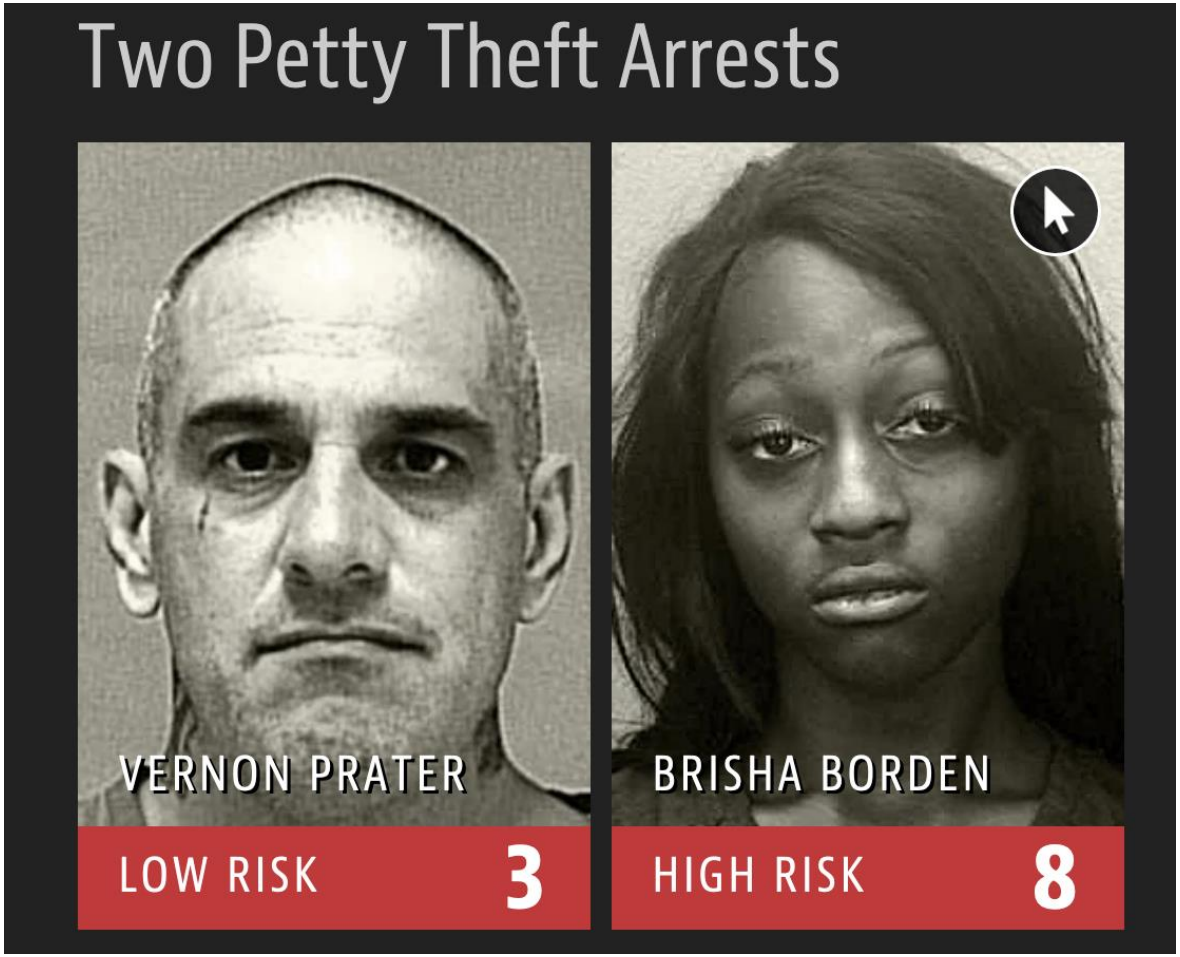
*by Julia Angwin, Jeff Larson, Surya Mattu and Lauren Kirchner, ProPublica*

May 23, 2016

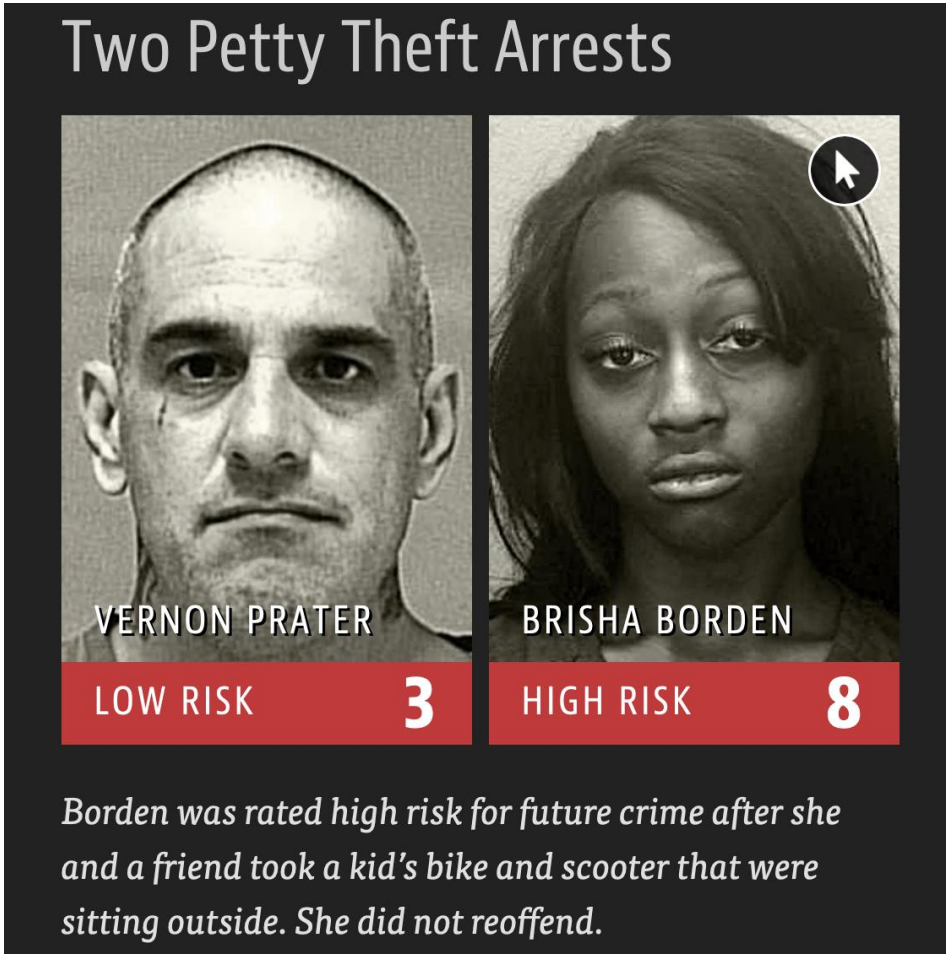
# Automated risk assessment

- AI used to rate a defendant's risk of future crime based on selected parameters
- Risk assessment scores used in US courtrooms to make decisions about the accused at every stage of the criminal justice system, from assigning bond amounts to criminal sentencing.

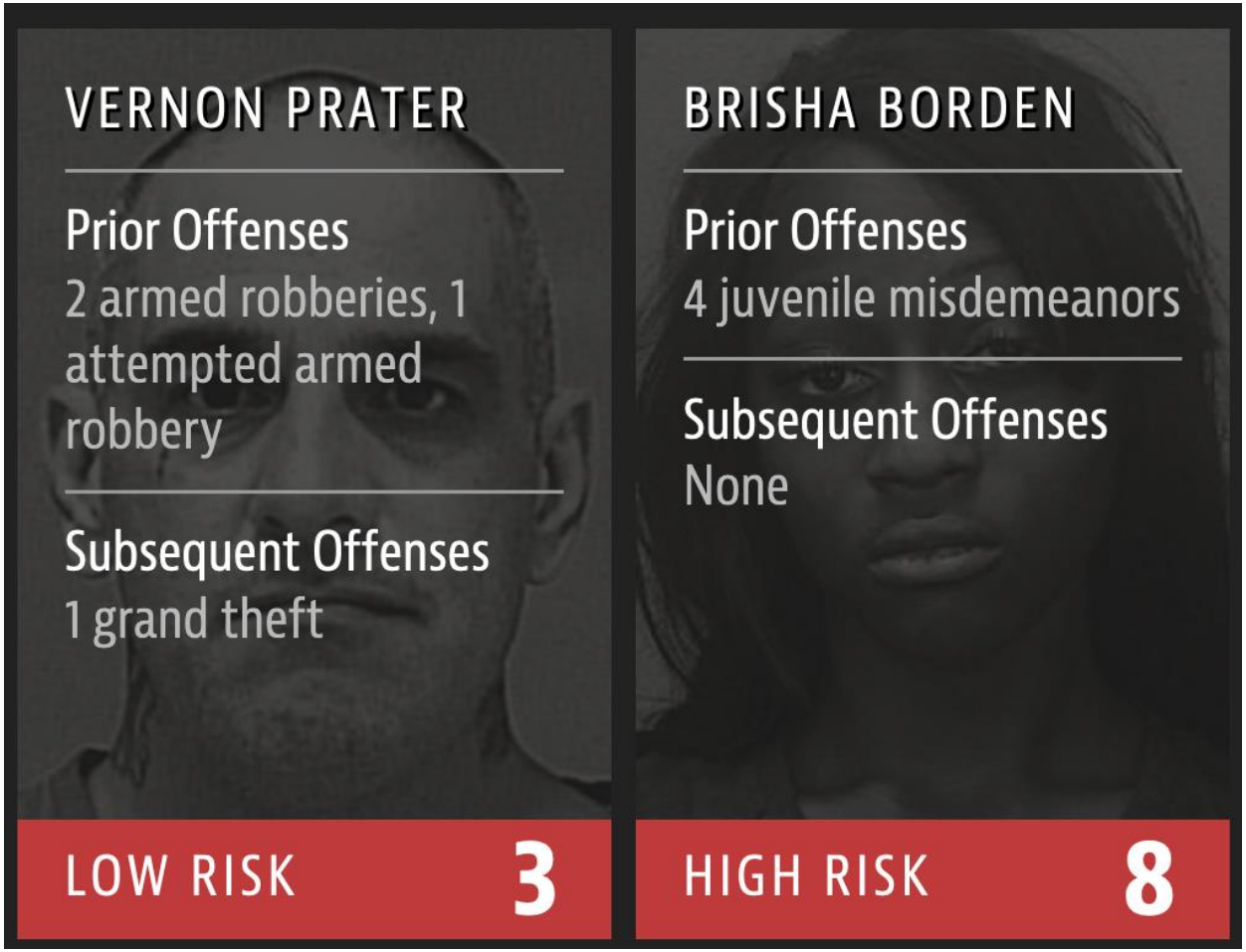
# Sample AI assessment



# Sample assessment



# Failed risk assessment



# RxBox in Telehealth


- REMOTELY measure patient's temperature, blood pressure, heart rate, oxygen saturation, uterine contractions, and electrocardiogram readings.
- Healthcare to patients in locations without doctors/ specialists
- Physical distancing

*Photo: DOST-X/Text by Rodolfo P. de Guzman/S&T Media Service) http://www.dost.gov.ph/knowledge-resources/news/67-2020-news/1816-dost-pchrd-rolls-out-more-rxbox-telehealth-devices-to-fight-covid-19-2020-05-09.html?tmpl=component&print=1*

# RxBox: ELSI


- Social acceptability
- Social communication
- Ownership of technology
- Danger of depersonalized care
- Privacy
- Data integrity – suitability of algorithm for diagnosis, prognosis & treatment

*Photo: DOST-X/Text by Rodolfo P. de Guzman/S&T Media Service)*

# AI in Nutrition Research: Using "Electronic Health Records"

- High-quality RCTs are difficult – they require subjects to adhere to diets for several years
- Other studies are observational – chances of human error
- AI (eg smartwatches) allows collection of extensive data sets and all-encompassing portrait of a person's health metrics

# AI in Nutrition Research: Using "Electronic Health Records"

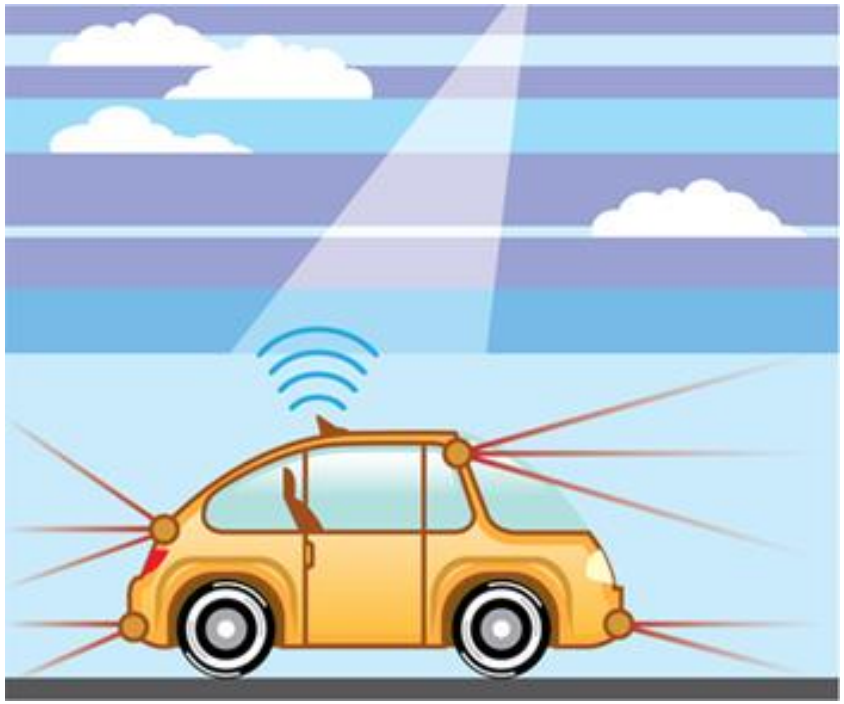
- Smartphone photos of meals to eliminate risk of human error in food logging
- Use of smartwatch to monitor activity levels, sleep patterns, medication consumption, and microbiome functioning
- Advanced algorithms to track health metrics to develop a personalized diet.

# AI in Nutrition Research: ELSI

- Social acceptability
- Social communication
- Ownership of technology
- Danger of depersonalized care
- Privacy
- Data integrity -- accuracy of algorithm

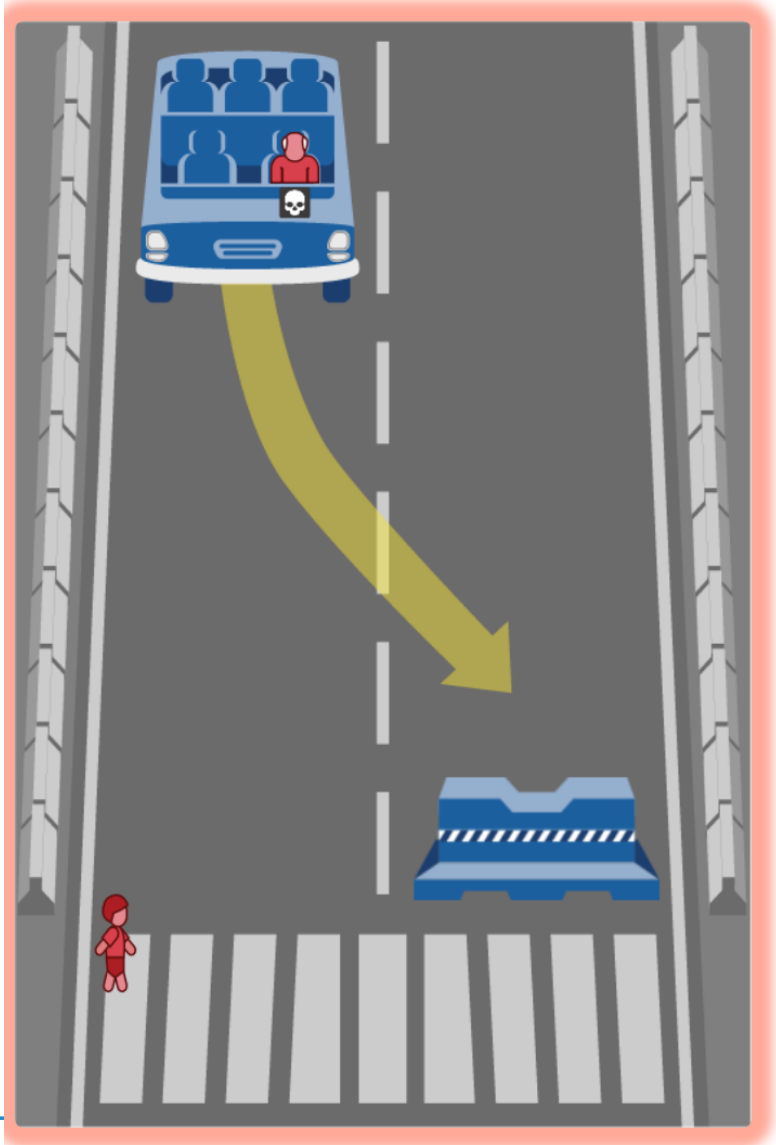
# Autonomous car: ethical issues

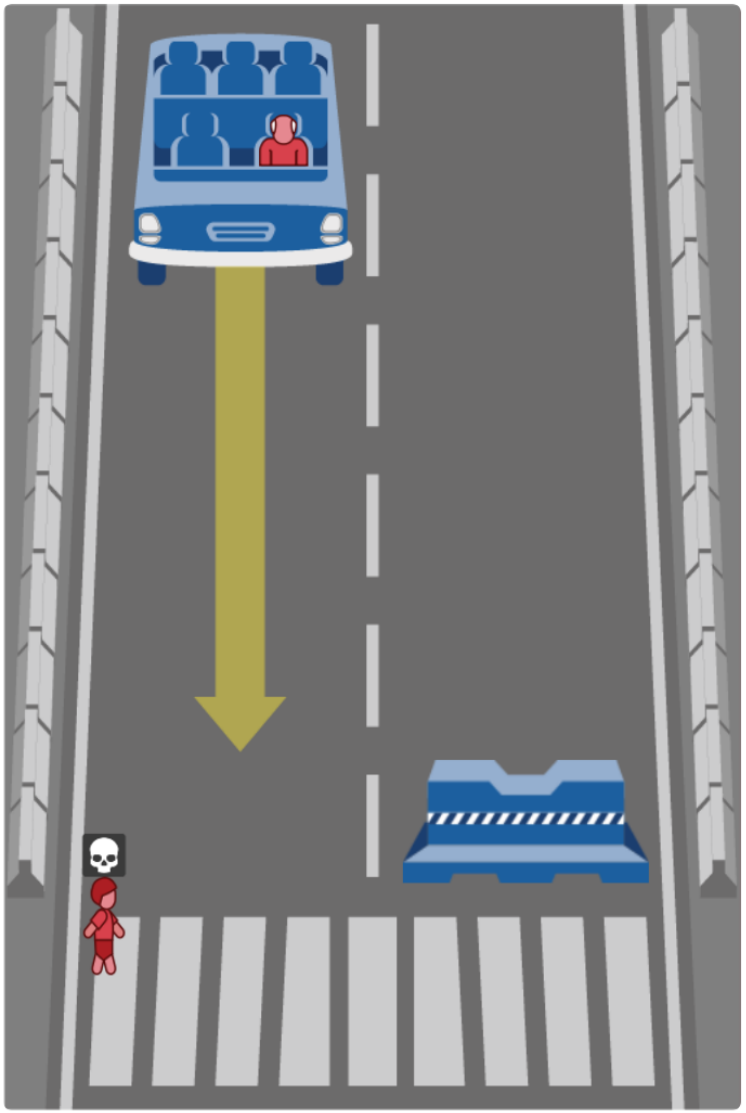
- What aspects of research on autonomous cars involve human participant research?



**Bob Ward, Self-Driving Cars: Pros and Cons, and Unknowables https://yaleclimateconnections.org/2016/04/electric-cars-pros-cons-and-unknowables/**

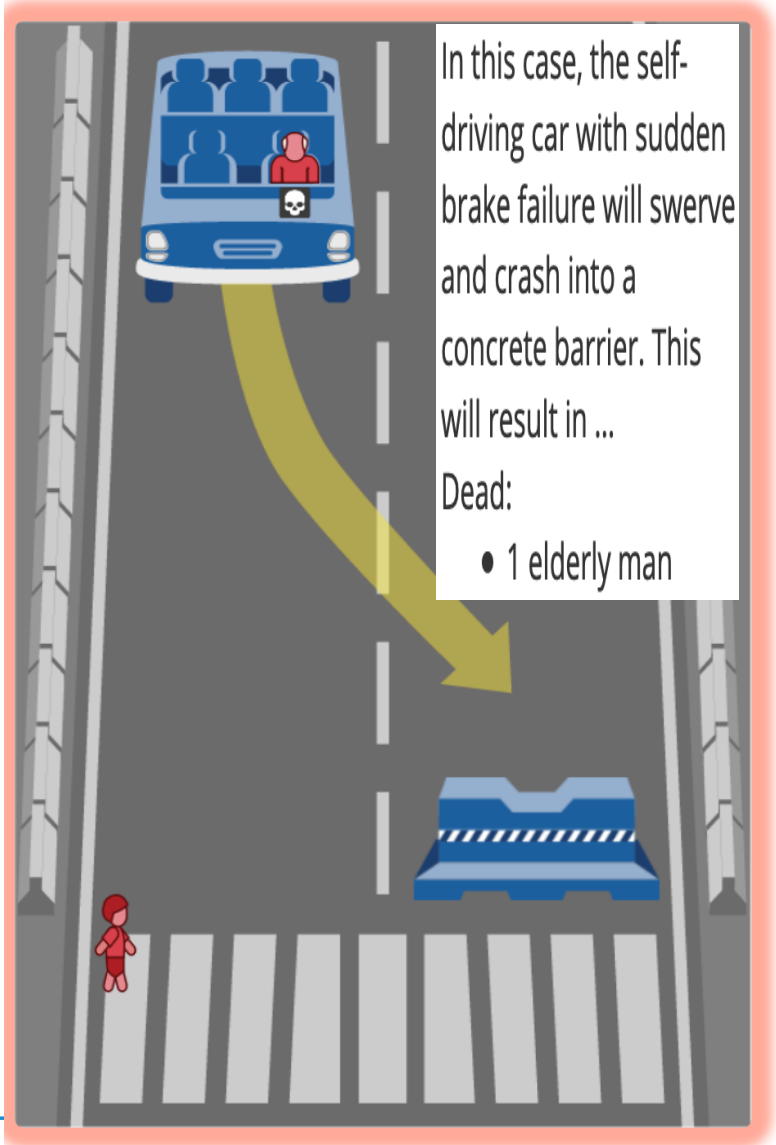
# What should the self-driving car do?

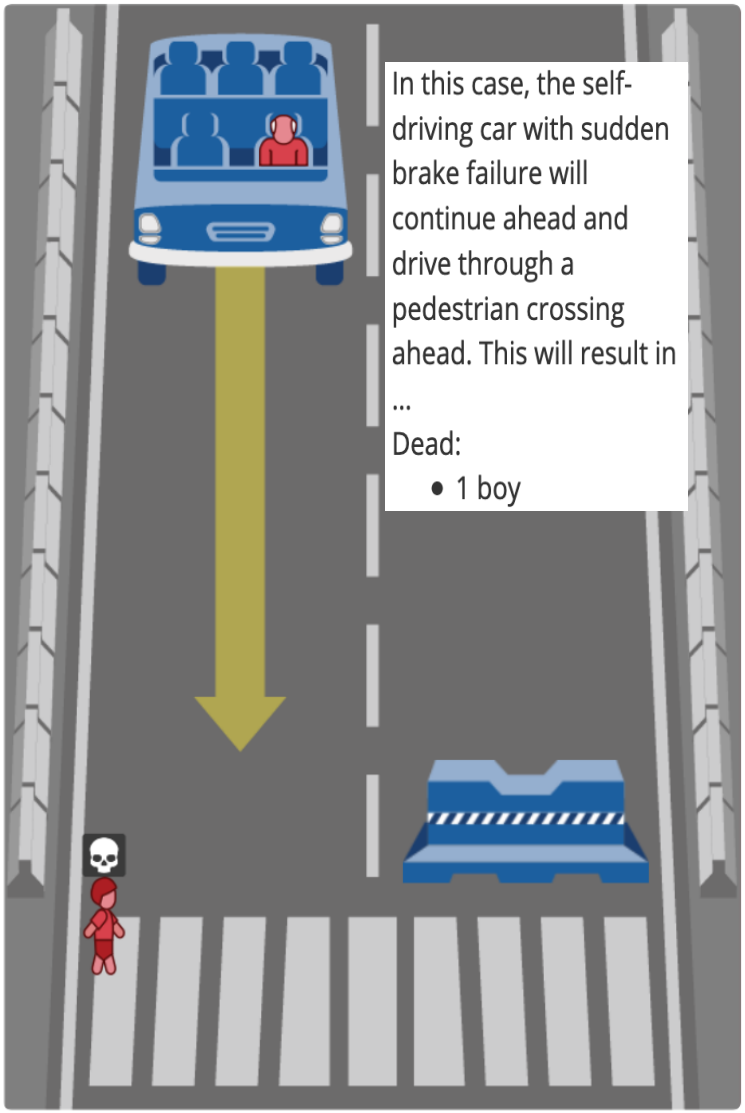




https://www.moralmachine.net/

# What should the self-driving car do?

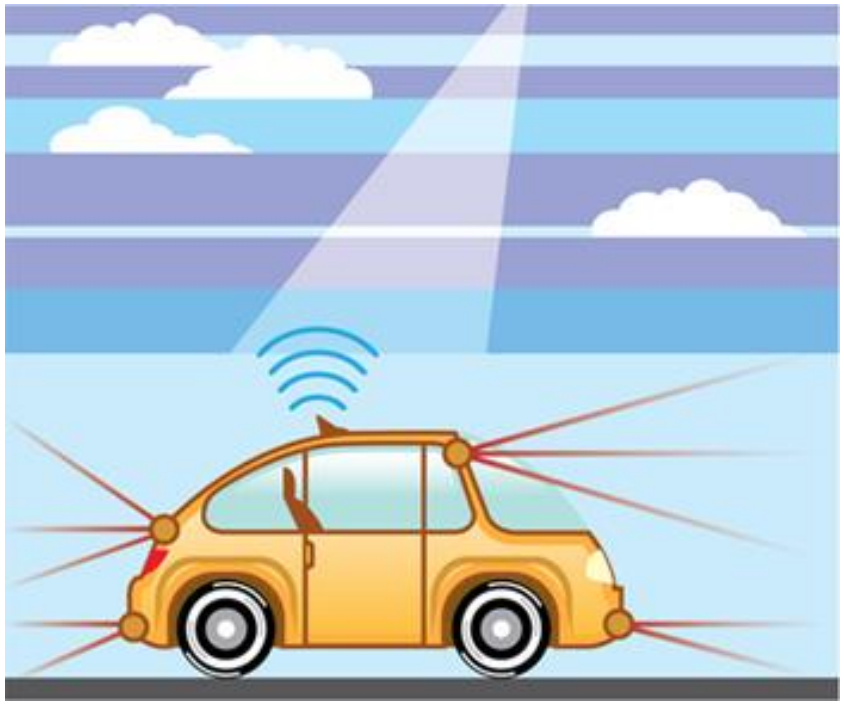



https://www.moralmachine.net/

# Autonomous car: ethical issues

- Who should be ethically responsible for accident harms?
  - The car owner?
  - Car company?
  - Ethics Algorithm Designer?
  - Insurance company?
  - The car?



Bob Ward, Self-Driving Cars: Pros and Cons, and Unknowables https://yaleclimateconnections.org/2016/04/electric-cars-pros-cons-and-unknowables/

# Artificial intelligence: merging of research and practice

- Use of driverless cars involves continuing research
- Use of health monitoring smart watches involves continuing research
- Use of RxBoxes involves continuing research

- Continuing research involves human participants and
- Requires innovative methods of ethics review

# Magandang umaga po!

decastro@kssp.upd.edu.ph