

Digital Health: Ethical Considerations

Camille Nebeker, EdD, MS

Associate Professor
Department of Family Medicine & Public Health
Director/Co-Founder ReCODE | health
School of Medicine, UC San Diego

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PRIMER: Ethical, Legal and Social Implications



Ethical

Consent & Literacy

Bystander Rights

Risk / Benefits

Access

Justice



Legal/Regulatory

Liability

Privacy: GDPR & CCPR

Intellectual Property

Federal Regs

Conflict of Interest



Social

Downstream Impact

Unknown Unknowns

Sociotechnical Systems

Privacy Expectations

Return of Value

Digital Health Snapshot

| Sources of Health Data



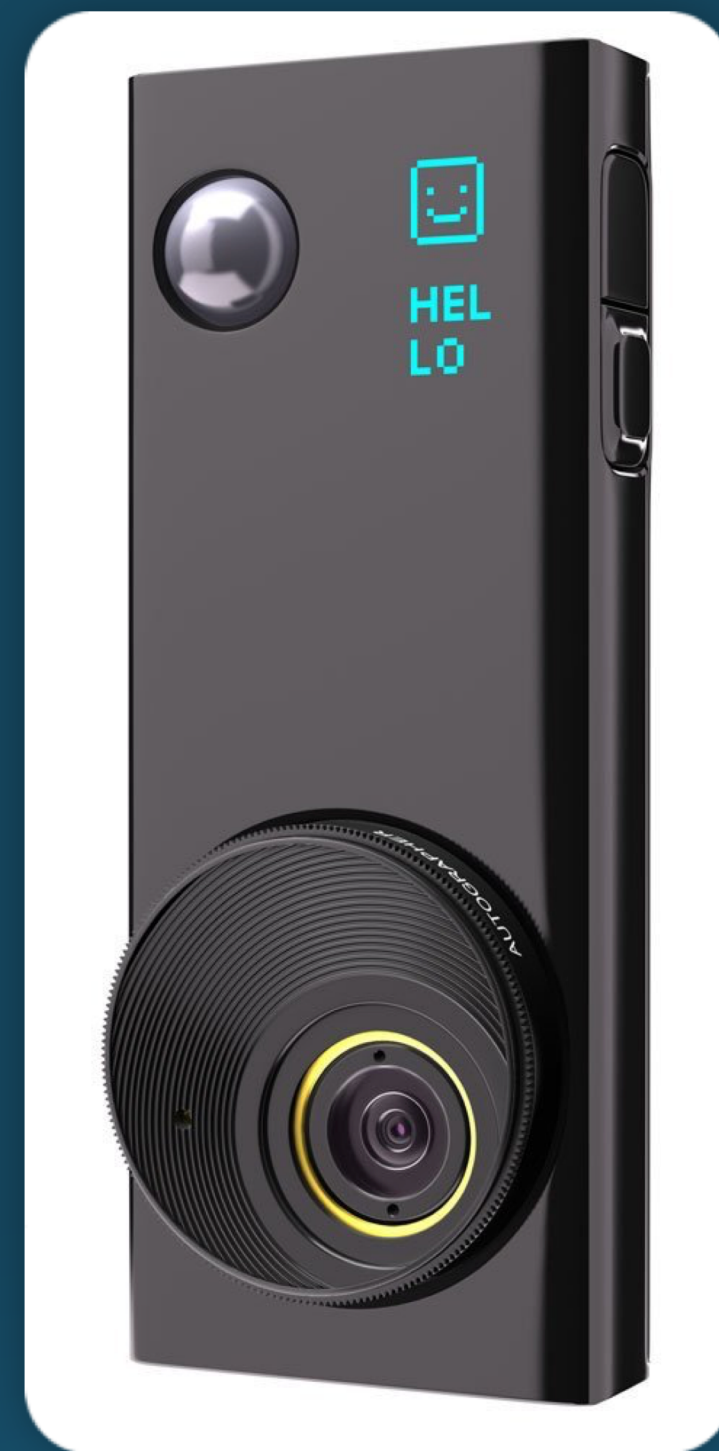
With permission of Dr. Kevin Patrick, UC San Diego
Professor, Preventive Medicine

| Mobile Methods



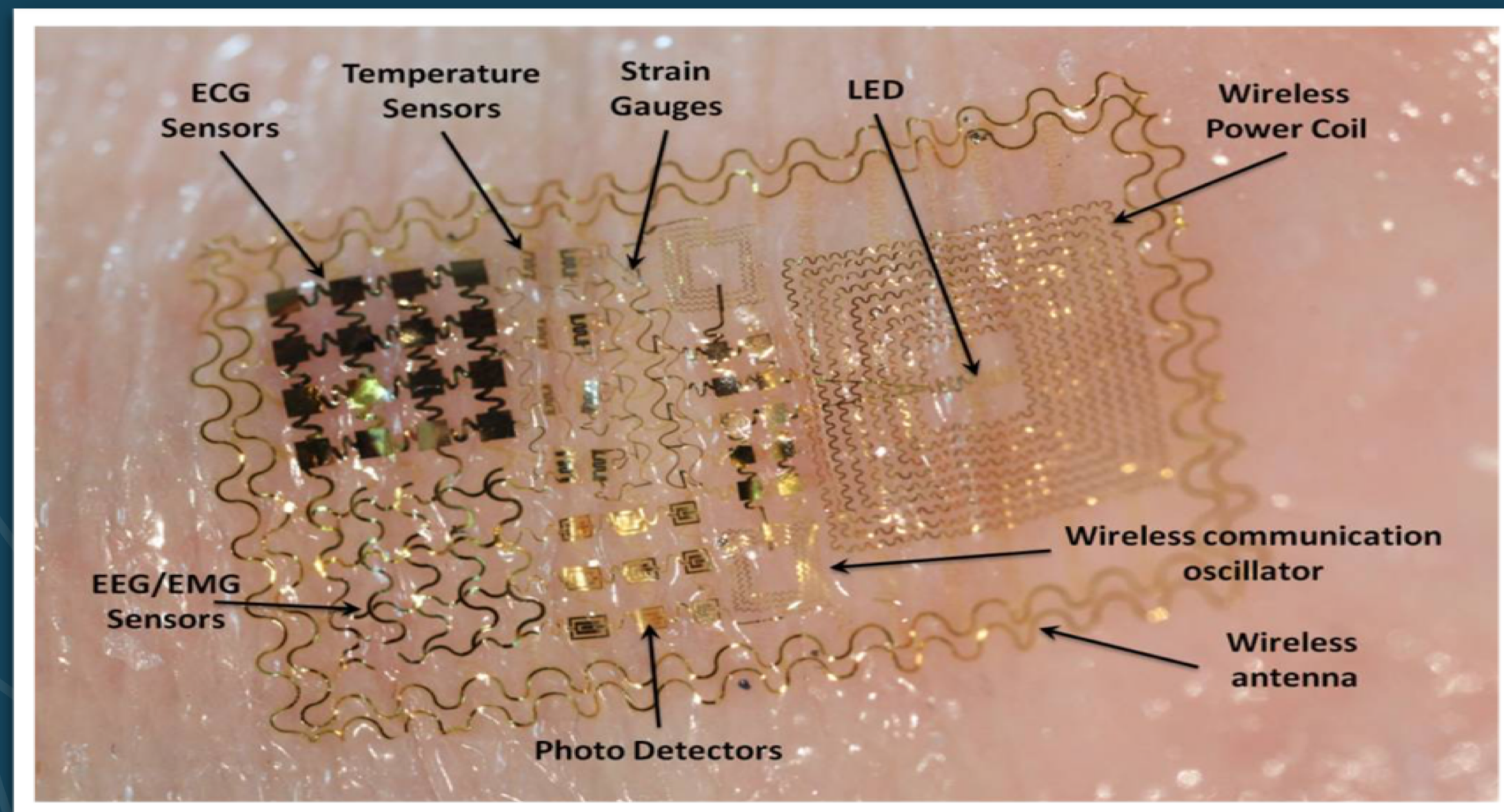
Access to apps, deploy surveys to study behaviors in real time via tools like Ecological Momentary Assessment.

Visual Methods



To study “free-living”
behavior “in the wild” from a
first person perspective.

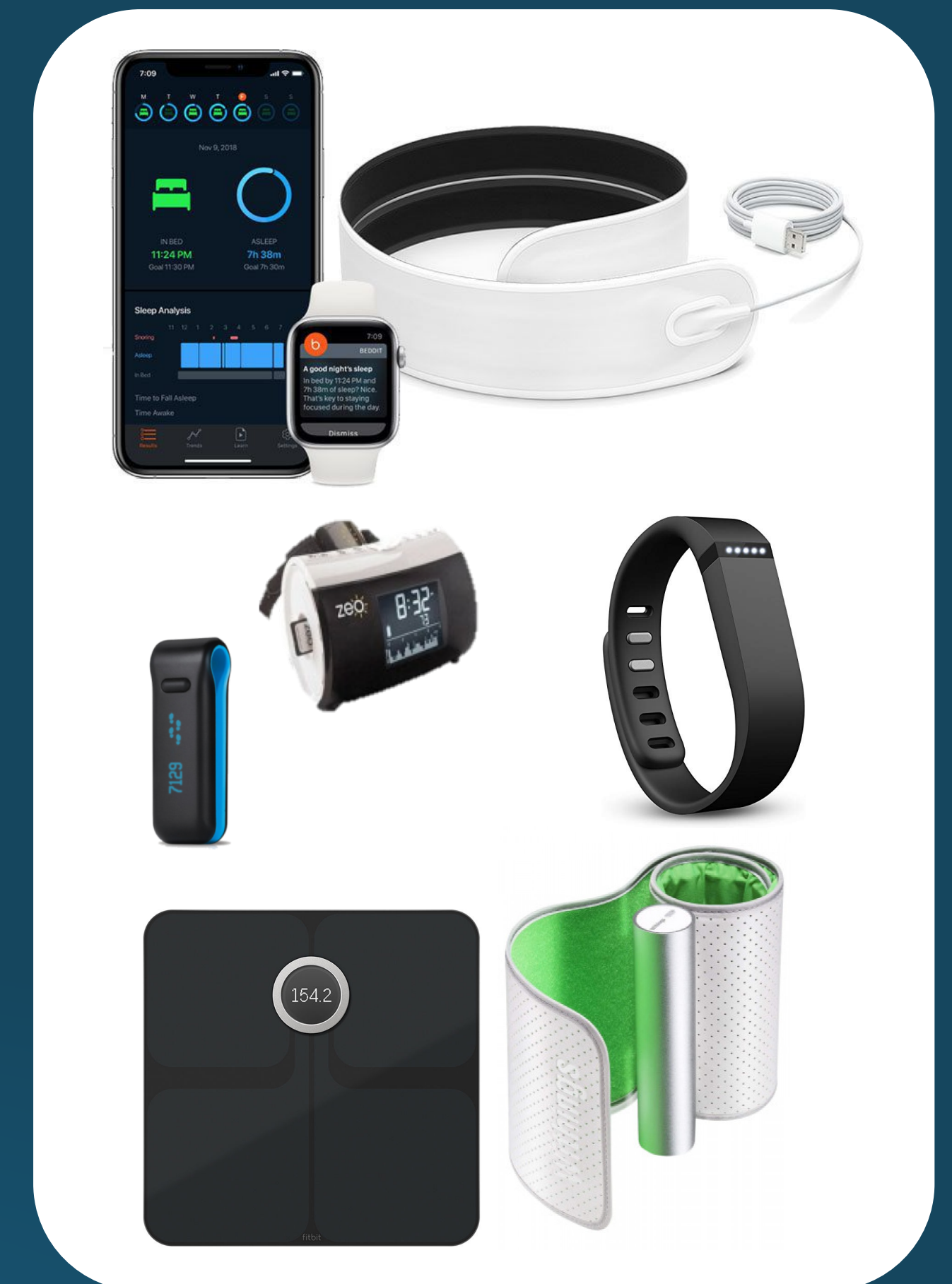
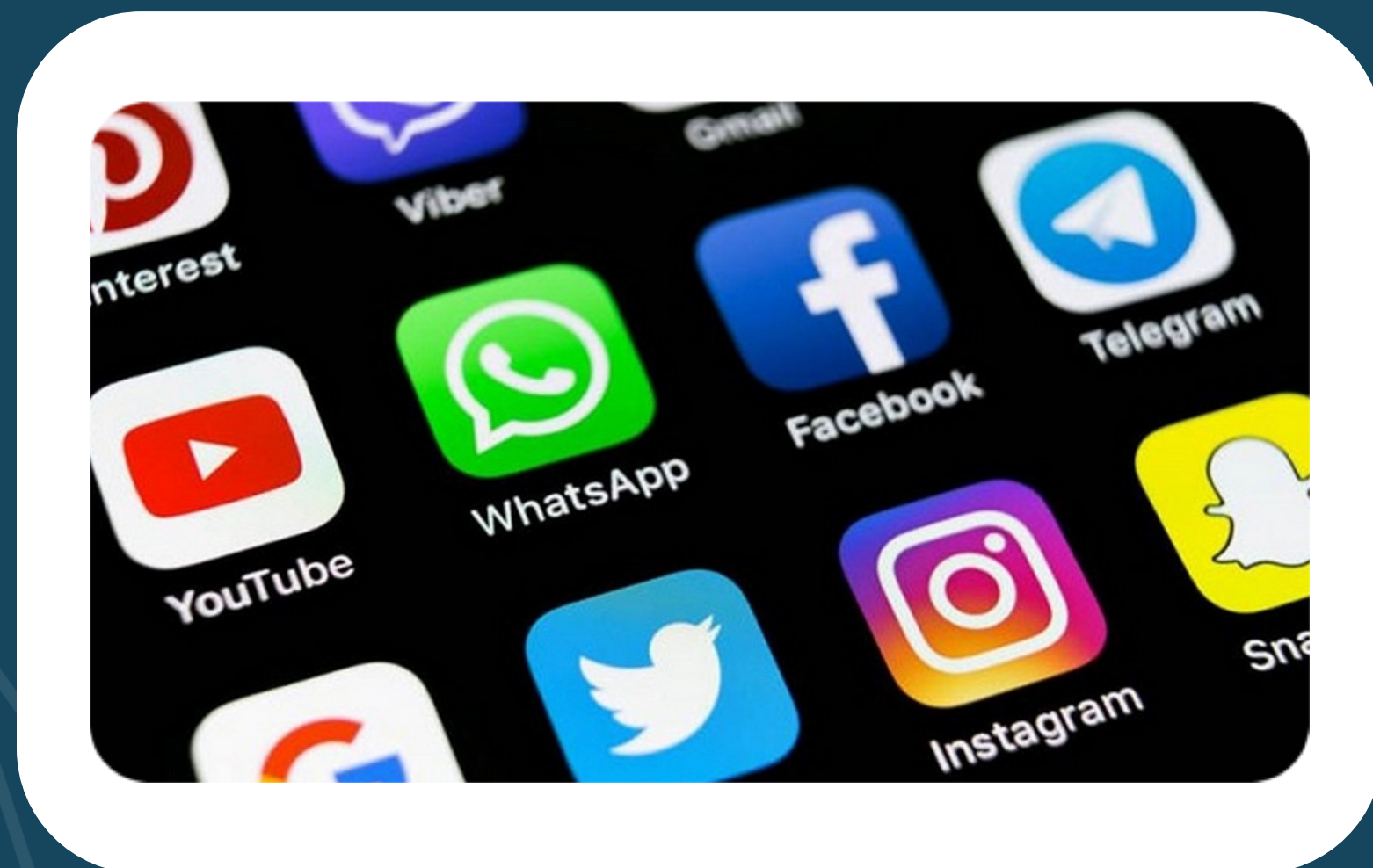
Sensing Methods



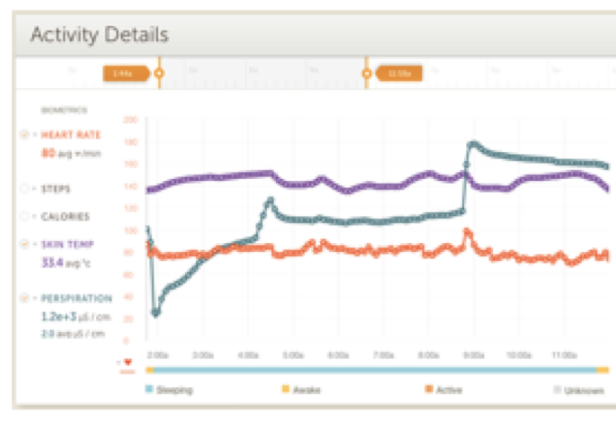
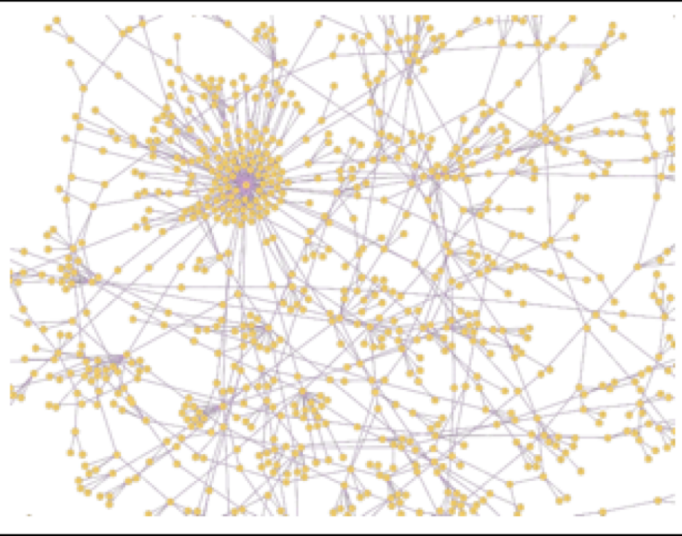
With permission of Dr. Todd Coleman, UC San Diego
Professor of Electrical & Computer Engineering

Passive
Pervasive
Ubiquitous

Digital Platform Methods



New Methods = New Data

Wearable Cameras	GPS Tracking	Smart Phones	Social Media
			 The CORE UCSD @UCSDtheCORE · Apr 5 Rasheed Al Kotob proudly represents our #COREethics team @UCSDH #PublicHealthWeek #mHealth #DigitalHealth #research_ethics @APHA
			

Commercial Products



**Jawbone
Up 24**



**Garmin
Vivofit**



**Fitbit
Flex**



**Basis
B1 Band**



**Misfit
Shine**



**Withings
Pulse 02**



**Nike
Fuelband
SE**



**BodyMedia
LINK
Armband**

Subject to Fitbit's adherence with the privacy settings you select within the Fitbit Services, you hereby grant to Fitbit a perpetual, irrevocable, non-exclusive, worldwide, royalty-free license, with the right to sublicense, to reproduce, distribute, transmit, publicly perform, publicly display, digitally perform, modify, create derivative works of, and otherwise use and commercially exploit any text, photographs or other data and information you submit to the Fitbit Services ...

Health Tech Landscape



The New York Times

Chasing Growth, a Women's Health Start-Up Cut Corners

A fully powered trial has to be conducted to examine this effect.

Participants (n=19) proactively logged into 7Cups for a median of 12 times and 175 minutes.



online and mobile meditation content in the health & wellness space. We are **not** a health care or medical device provider, nor should our Products be considered medical advice. **Only**

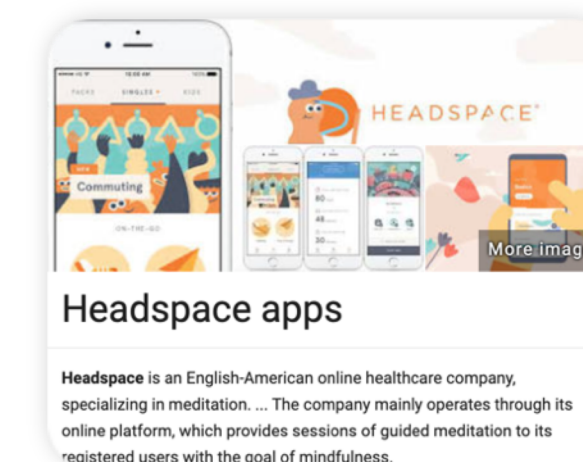
Wellness Tools to Transform your Life



uBiome, the health start-up raided by the FBI

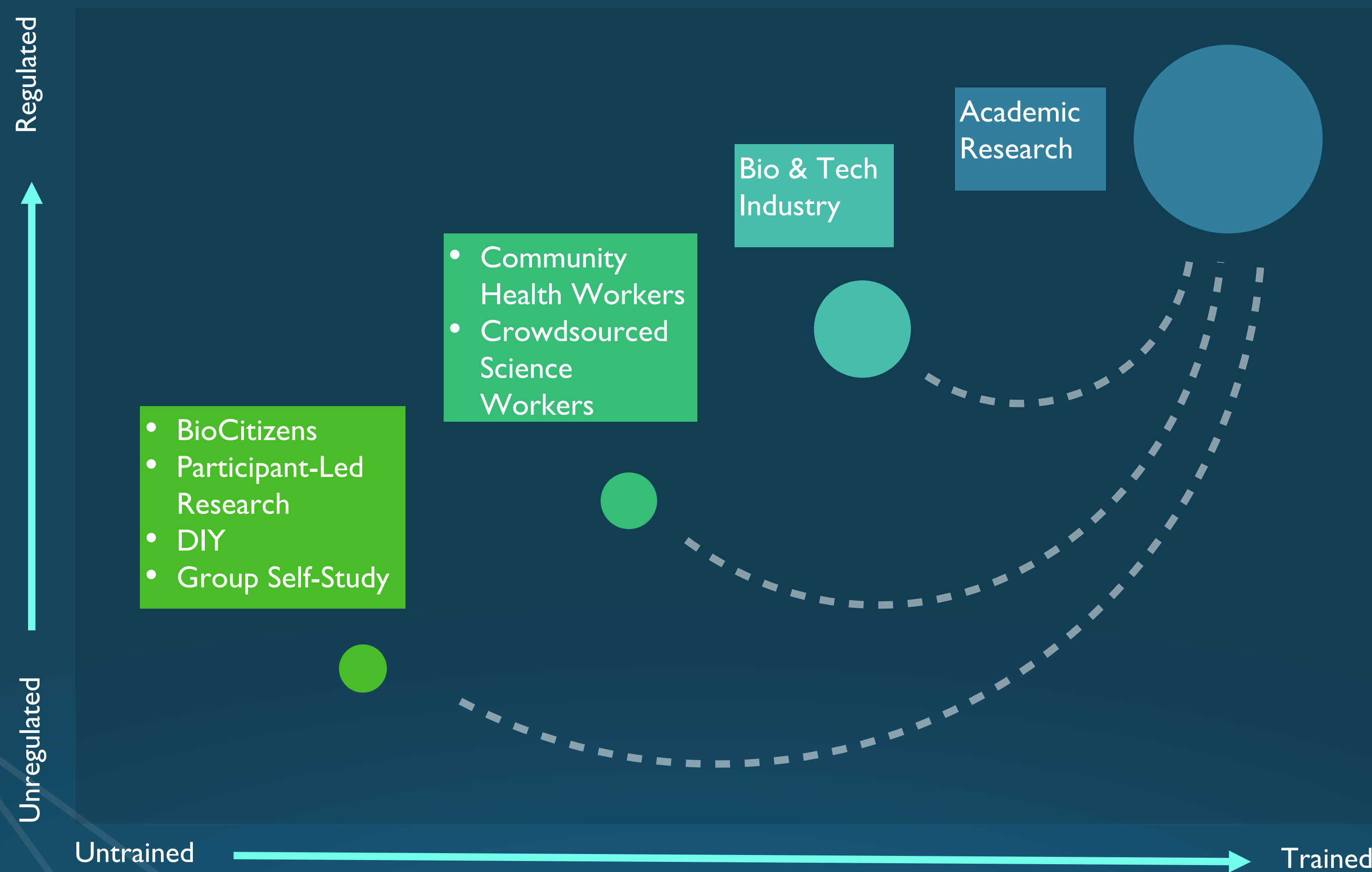
Twitch Cares: Mental Health Support & Information

Twitch cares. If you feel like you're struggling, or you've encountered someone who you believe might self-harm or is suicidal, please contact law enforcement or a [suicide hotline](#) immediately.



Challenges and Opportunities

New Actors = Unique Challenges



| Digital Health Research Questions

Better Care:

Can machine learning and AI
can make clinicians more
efficient and effective?

Governance:

Are existing systems
(conventions, norms, regs)
relevant and responsive?

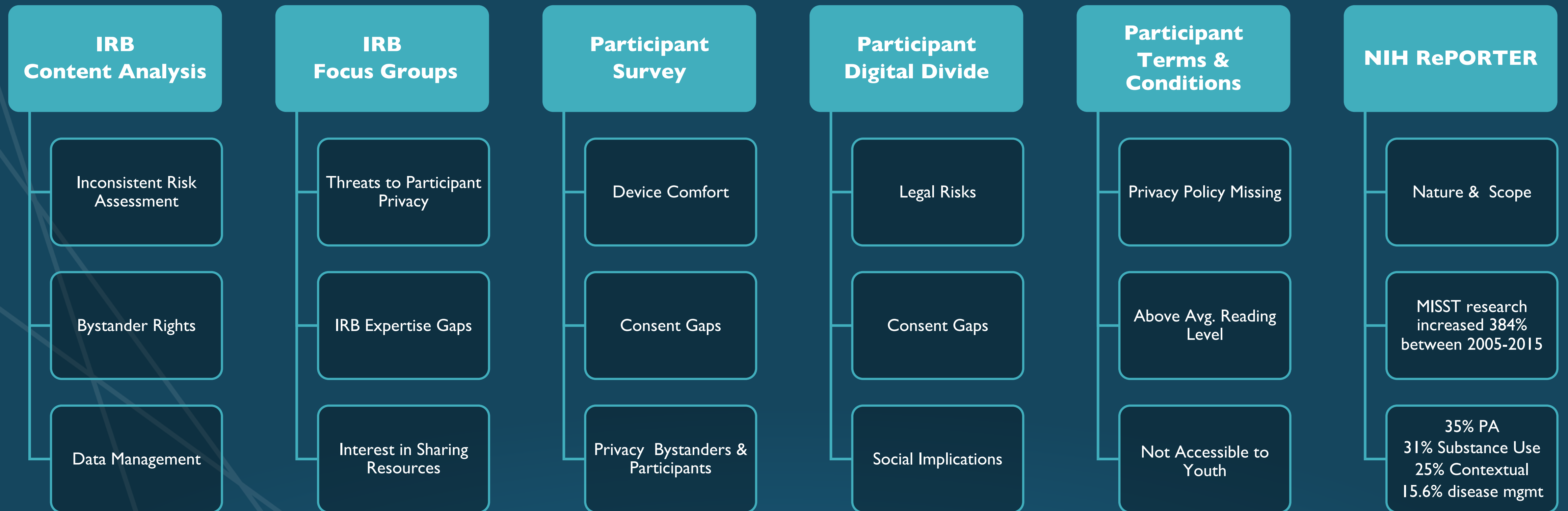
Data Management:

Can we promise data
anonymity? Is de-
identification a solution?

Consent:

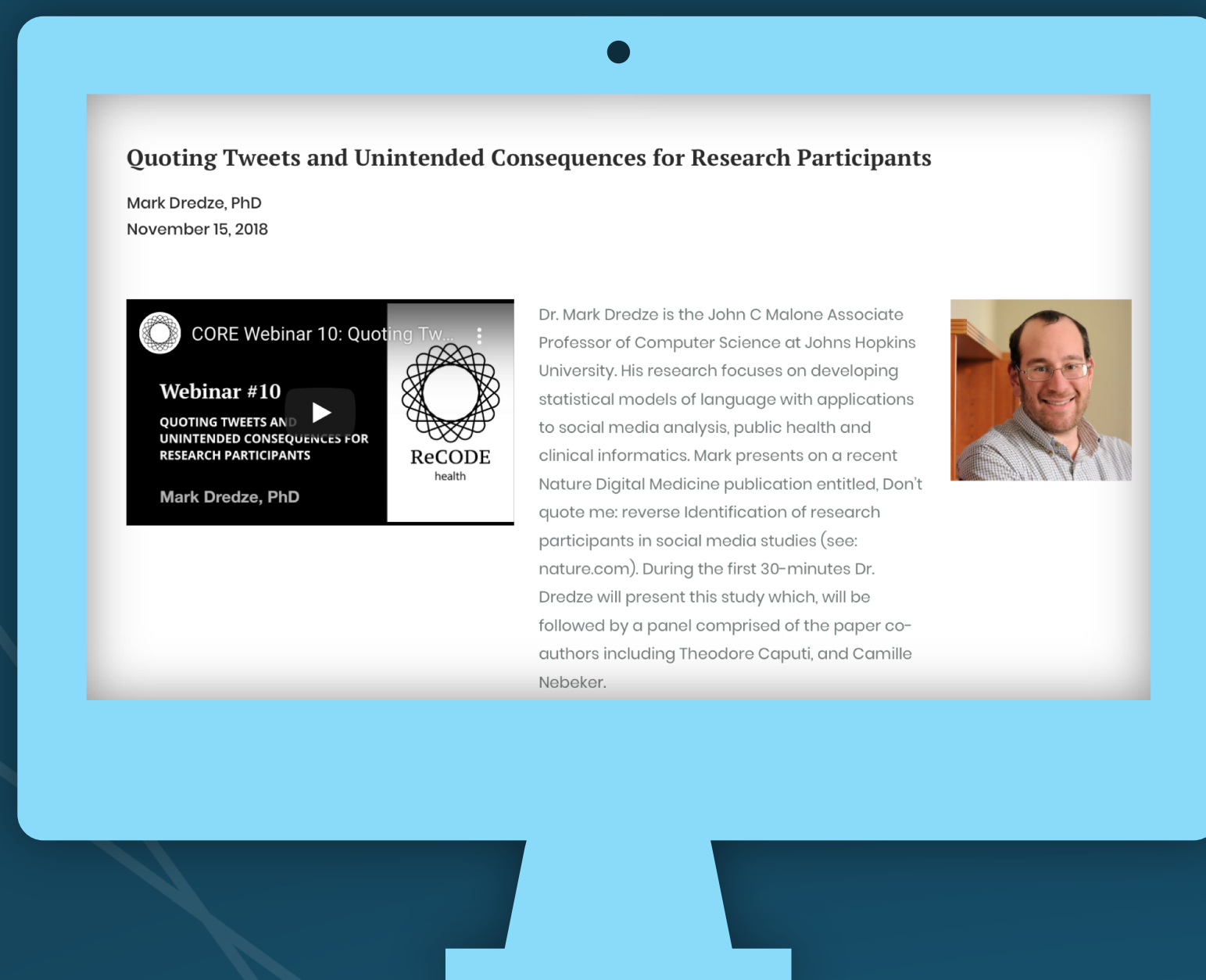
Can it be truly informed?

Digital Health Research



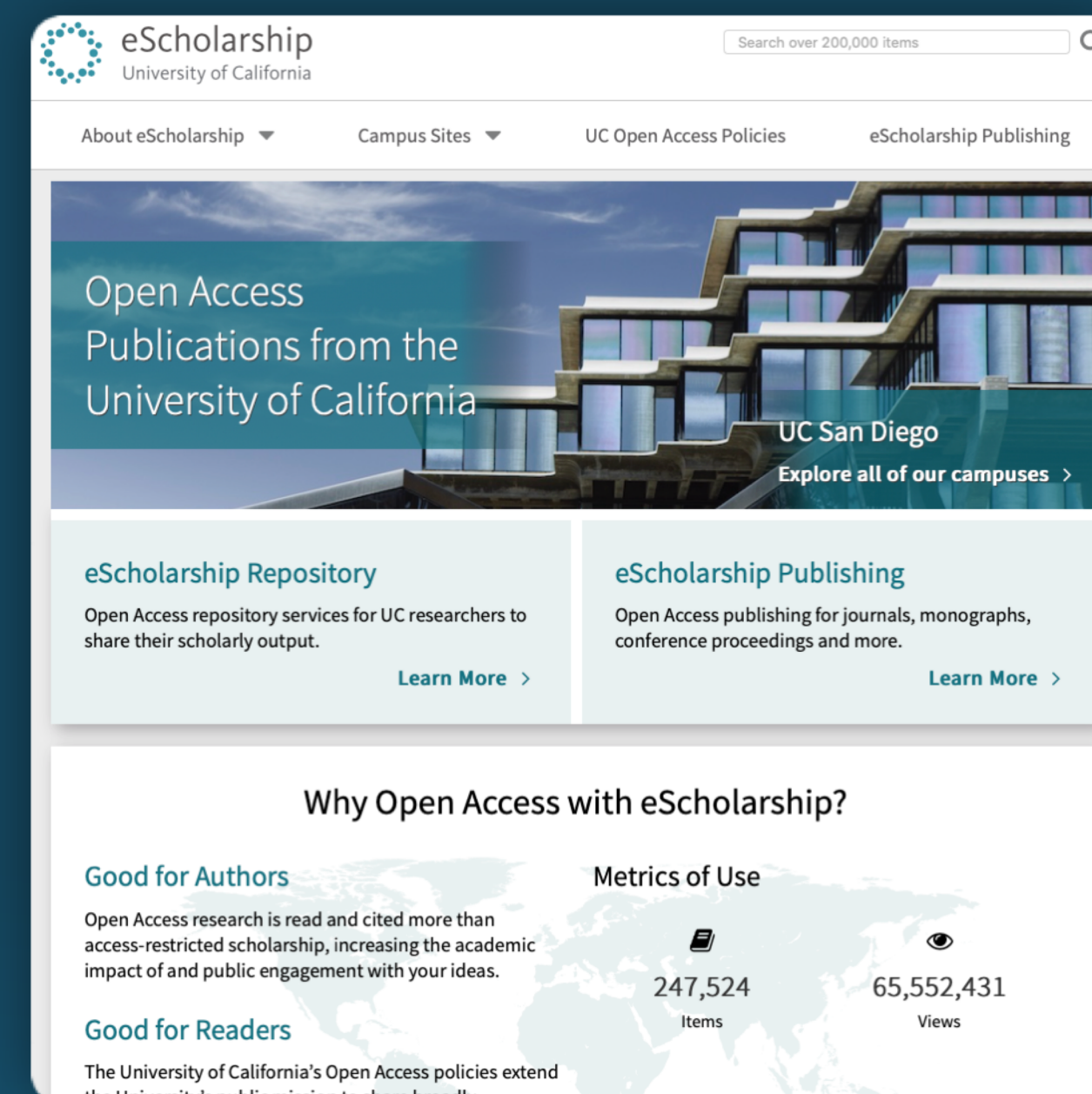
| Accessible Research Results

Webinars



recode.health/webinar

Publications on eScholarship



escholarship.org/uc/recodehealth

Digital Health Decision-Support Framework and Checklist

PRIMER: Ethical, Legal and Social Implications



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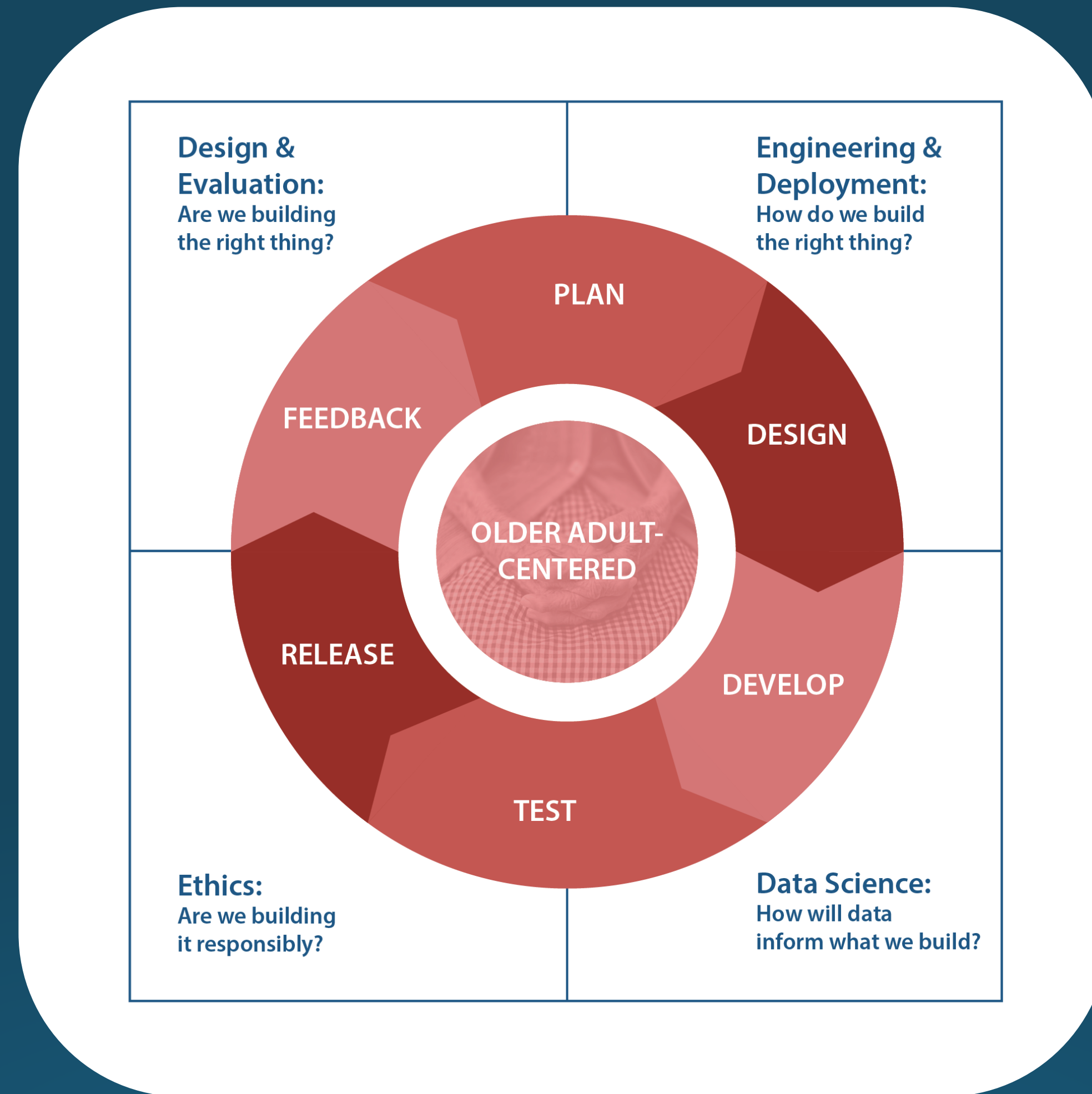
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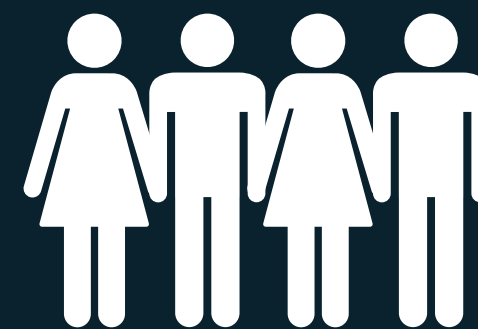
Return of Value

| Human Centered Design Process



Iterative Approach

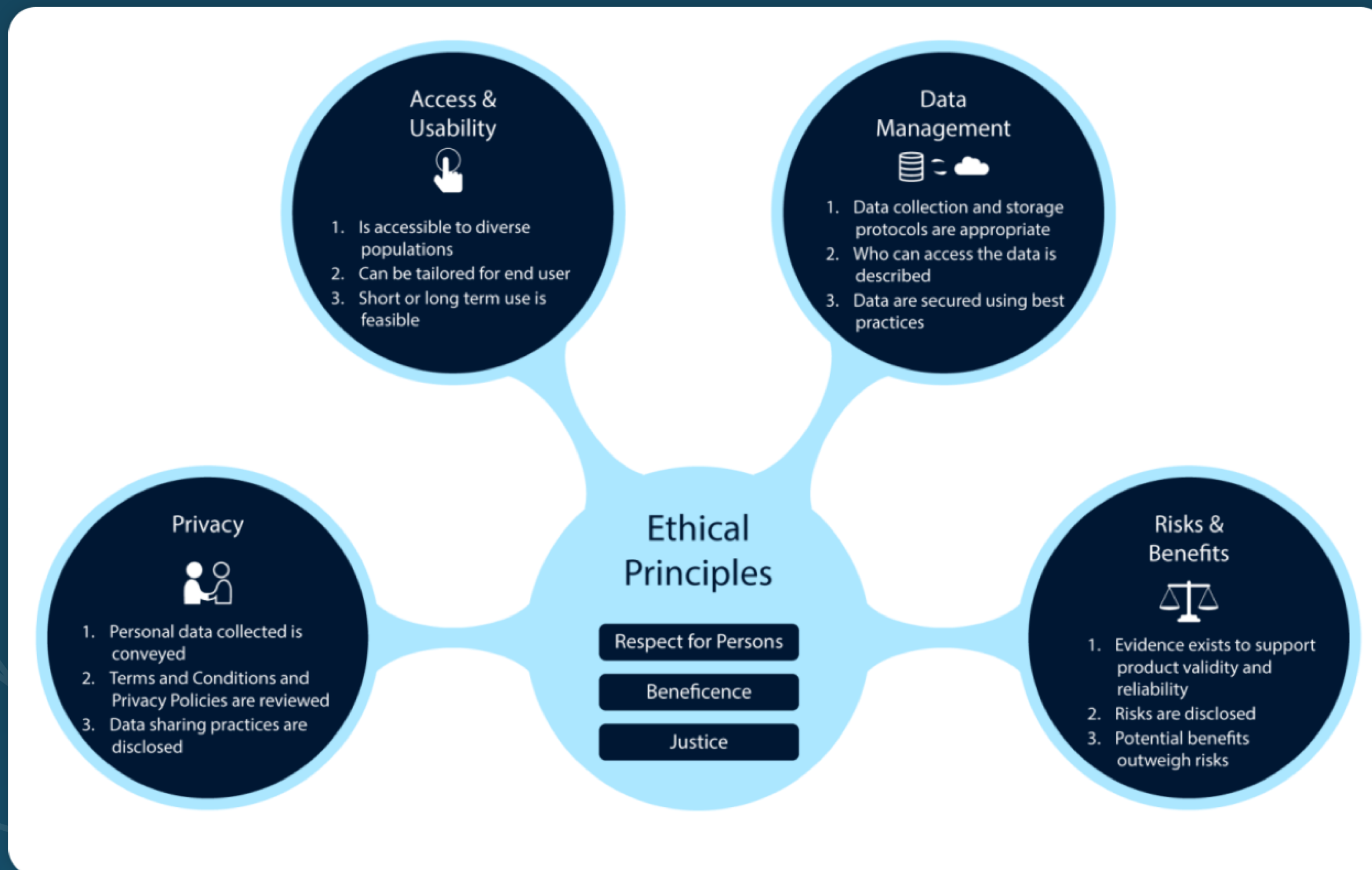
Phase I



Phase II



Factors Influencing Ethical Practices



Access and Usability

The domain of *access and usability* is about the product design and whether end-users are able to use the tool.

- How does it work?
- How that this information communicated to the user (informed consent or terms of service)?
- Has it been used with the target population? Are accessory tools needed (smartphone, internet access)?
- Can the product can be used both short and long-term?

Access & Usability

Respect for Persons

Contract provides:

Relevant information within Terms of Service/Privacy policy in plain language?	☐
Access to definitions?	☐
Access to visual and audio versions of information?	☐
Possibility of bystander involvement?	☐

Beneficence

Includes a plan for return of group and individual study information?	☐
Study design includes features to increase access and usability for older adults?	☐
Short and long-term use has been or will be tested with older adults?	☐
Rights of all stakeholders are considered?	☐

Justice

Device or App was tested with older adults?	☐
Requires internet?	☐
Requires smartphone?	☐
AI trained on data inclusive of older adults?	☐

Respect for Law and Public Interest

AI is accountable?	☐
Algorithms are documented and transparent?	☐

Privacy

Privacy is about the personal information collected and expectations of the patient or participant to keep information secure. If shared:

- What is collected?
- What is shared?
- Why is it shared?
- What control does the end user have?

Privacy

Respect for Persons

Beneficence

Contract clearly conveys:

Personal information collected?	☐	Privacy expectations are respected?	☐
Data sharing plan?	☐	Participant data are not shared or sold to a 3 rd party?	☐
Privacy policy risks?	☐	Participant contact information is not shared/exploited?	☐

Justice

Respect for Law and Public Interest

Bias is managed to reduce...

Economic harm?	☐	Increase trust?	☐
Social harm?	☐	Protect privacy?	☐
Discrimination?	☐		
Profiling?	☐		

Risks and Benefits

The goal of this domain is to evaluate the types of possible risks as well as the extent of possible harm.

- Types of harm?
- Severity?
- Duration ?
- Intensity?
- AI Accountability and Transparency?

Assessment of risks and benefits is influenced by the evidence available to support the reliability of the product, risk mitigation strategies and recognition of unknown risks.

Risks & Benefits

Respect for Persons

Contract clearly conveys:

Risks and risk management strategies?	☐
Evidence?	☐
Unknown risks?	☐
Possible benefits to the person, people like them and to society?	☐

Justice

Legal harms are known?	☐
Potential risk of discrimination is transparent?	☐
Risks of harm no greater for 65+ demographic?	☐

Beneficence

Product is respectful of privacy preferences?	☐
Evidence to support tech reliability/validity?	☐
Evidence is peer-reviewed?	☐
Risks are known and mitigated?	☐
Risks are unknown and acknowledged?	☐
Potential benefits outweigh possible risks of harm?	☐

Respect for Law and Public Interest

Data and privacy protections are compliant?	☐
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| Data Management

Data management includes how data are collected, stored and shared and the extent of incorporation within other systems.

- What is collected?
- What is shared?
- Why is it shared?
- What control does the end-user have?
- Interoperability?

Data Management

Respect for Persons

Beneficence

Contract clearly conveys:

Data collection process?	☐	Data collection by party external to the research team?	☐
Data storage and security?	☐	Potential of data collected on or about a bystander (caregiver?)?	☐
Who will have data access?	☐	Data are accessible to the patient?	☐
Protocols for data sharing?	☐	Data are transferrable to the EHR?	☐
		Data ownership is clear?	☐

Justice

Respect for Law and Public Interest

System vulnerabilities are publicly disclosed?	☐	Data encryption meets expected standards?	☐
Data are not used to target groups or people?	☐	Storage is HIPAA and CFR compliant	☐
		Data are deidentified?	☐

| Path Forward



Courtesy of DJ Patil

Privacy vs Public Health

ARTICLES | [VOLUME 2, ISSUE 2, PE85-E93, FEBRUARY 01, 2020](#)



PDF [1 MB]

Harnessing wearable device data to improve state-level real-time surveillance of influenza-like illness in the USA: a population-based study

[Jennifer M Radin, PhD](#) [Nathan E Wineinger, PhD](#) [Prof Eric J Topol, MD](#) [Steven R Steinhubl, MD](#)

[Open Access](#) • Published: January 16, 2020 • DOI: [https://doi.org/10.1016/S2589-7500\(19\)30222-5](https://doi.org/10.1016/S2589-7500(19)30222-5)



Science | AAAS

Cellphone tracking could help stem the spread of coronavirus. Is privacy the price?

Researchers strategize ways to trace infections and contacts amid data protection laws

Yesterday at 10:30 AM (144 kB) ▾



[@Gerrille_Nabekov](#) are you doing any work in the realm of privacy-erect new digital health an

STAT

Hospitals turn to big tech companies to store and analyze their data - STAT

STAT found that the particulars of the deals are as varied as they are widespread, with no uniform standard for preventing misuse of patient data.

Mar 12th (64 kB) ▾

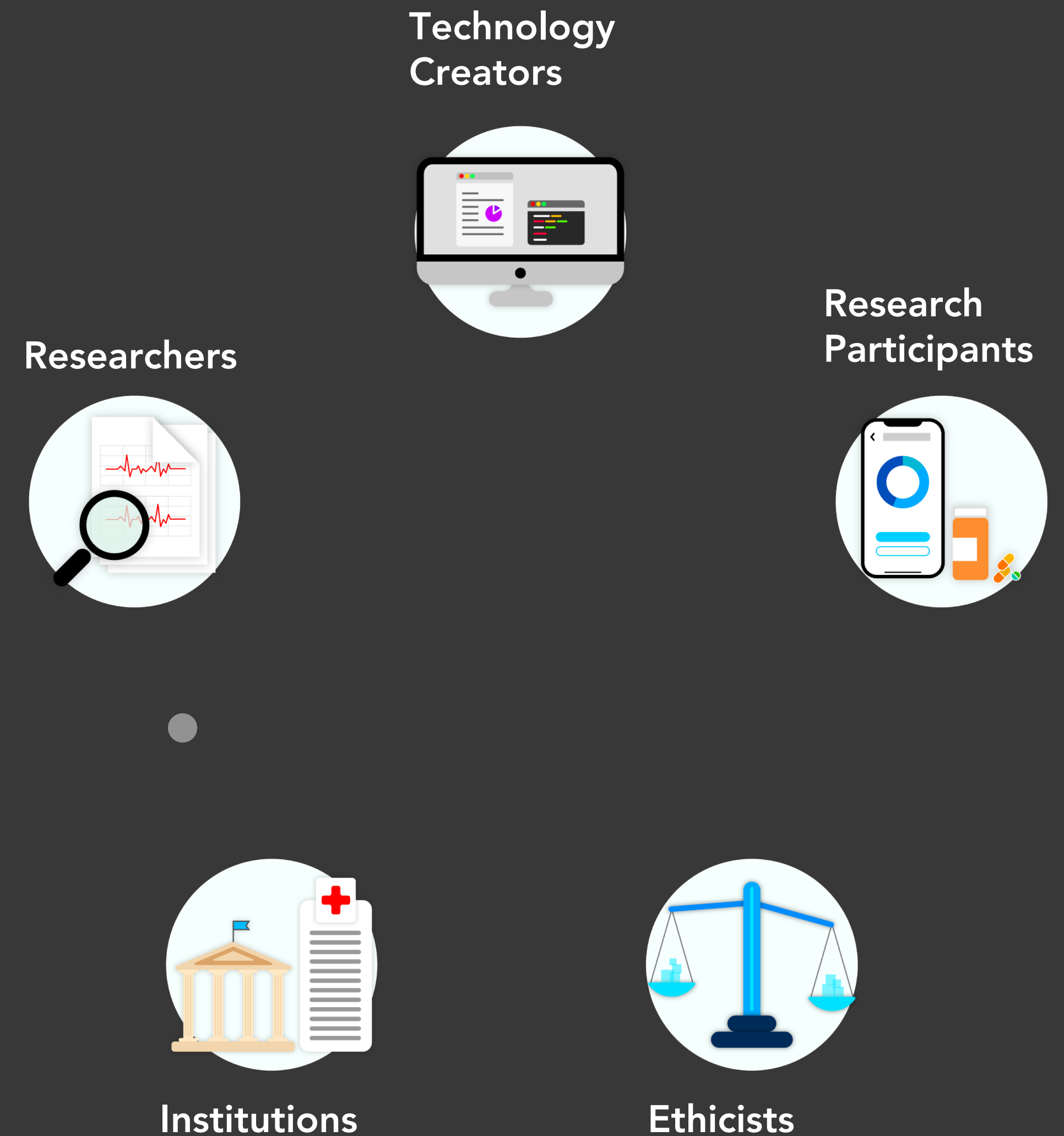
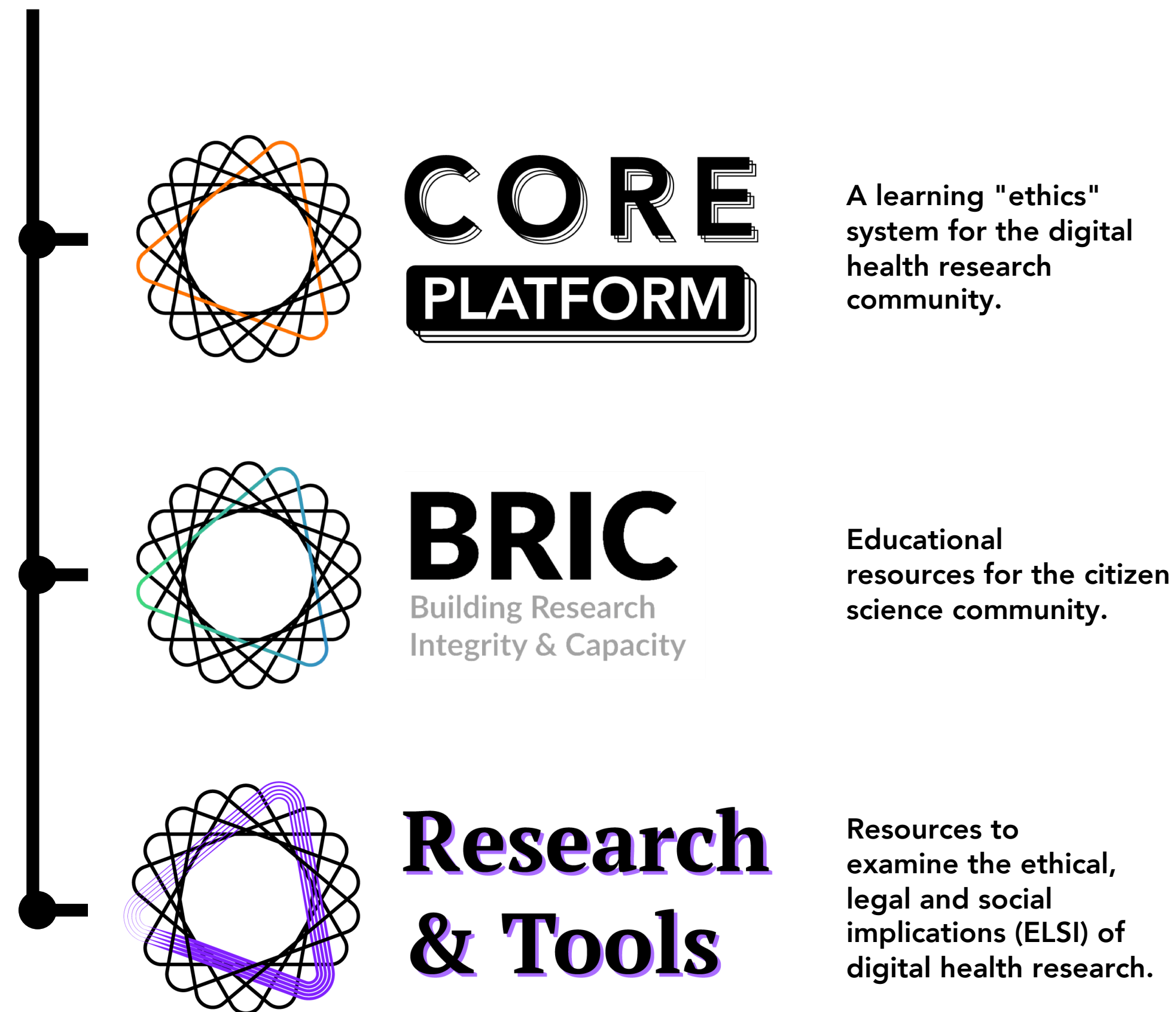


Privacy vs Public Health



ReCODE | health

The **Research Center for Optimal Digital Ethics | health** is shaping responsible and ethical research practices in the emerging field of digital health.



Thank You!

Camille Nebeker



@cnebeker



[linkedin.com/in/nebeker](https://www.linkedin.com/in/nebeker)



nebeker@ucsd.edu