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Ethical Aspects to Consider when Selecting and Recommending Digital Health Technologies

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1050 – 1150 ET

Presenter

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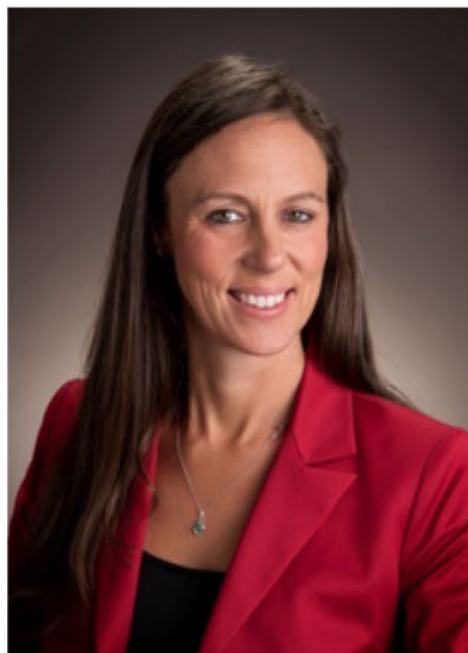
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Dr. Bartlett Ellis is an Associate Professor and the Executive Associate Dean for Academic Affairs at the Indiana University School of Nursing, Indianapolis.

She is a behavioral scientist and board-certified Clinical Nurse Specialist who synergistically aligns her academic practice with patient care and research.

As a nationally and internationally recognized expert in the field of medication management and adherence, her research focuses on developing and testing person-centered interventions to support medication management utilizing digital health technologies. She co-led the development of the Digital Health Checklist and Framework to aid researchers' decision-making about digital health technologies to ensure that they are used ethically, safely, securely, and effectively, which affects translation to practice.

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Disclosures

- Dr. Rebecca Bartlett Ellis is a paid consultant on federally funded awards in which the digital health checklist and framework are being used.
 - “Studying Methods for Ethical and Human Subjects Protecting Issues in Digital Health PCOR/CER” Digital Health Stakeholder (PI: Nebeker, UCSD); 10/2021-10/2024
- Other active research funding
 - “Medication Adherence Given Individual SystemCHANGE in Advancing Nephropathy (MAGICIAN) Study (PI: Ellis, 1R21NR019348); 9/23/2021 – 7/31/2023
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Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Identify four domains of the digital health framework.
2. Analyze the ethical implications of using digital technologies in health contexts.
3. Apply the Digital Health Checklist and Framework in practice to help guide decision-making about digital health technologies.

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Background

- Digital technologies are disrupting the ways in which health research is conducted, and subsequently, changing healthcare (Agarwal et al., 2010)
- State of digital technologies (Kraus et al., 2021):
 - Operational efficiency by healthcare providers;
 - Patient-centered approaches;
 - Organizational factors and managerial implications;
 - Workforce practices; and
 - Socio-economic aspects.

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Digital Opportunities

- Emerging technologies have created a lived environment that is smart and connected, and
- Technologies offer opportunities for health care application
 - Now people can monitor or be monitored and/or intervened with 24/7, on the fly and in real time.
 - Endeavors of academia, industry, not-for-profit organizations and individuals.
 - ✓ Enable major business improvements (Chawla & Goyal, 2021)
 - Relatively unregulated digital research ecosystem.

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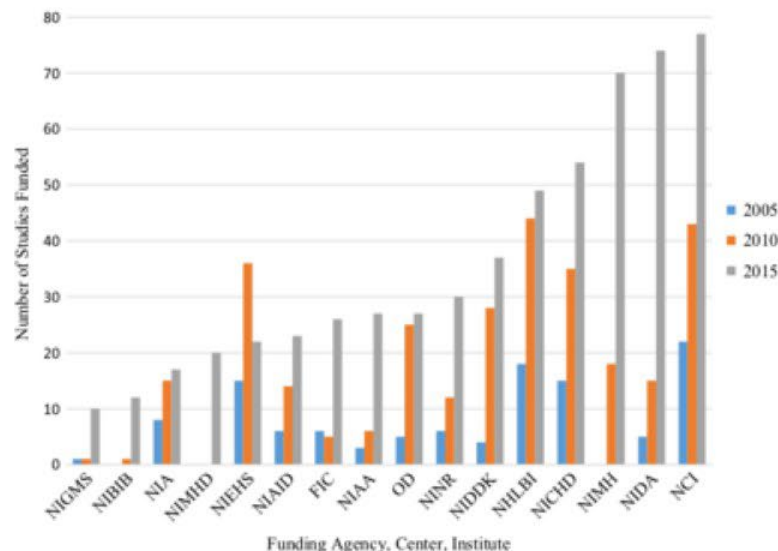


Increase in Digital Health Research and Lack of Associated Guidance

NIH support of digital technology-enabled research
S Dunseath et al.

npj

3



(Dunseath, et al., 2018; Nebeker, Dunseath, & Linares-Orozco, R., 2020)

Fig. 1 Number of MISST studies funded per institute in 2005, 2010, and 2015 of the institutes funding at least 10 projects at any of the three time points



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Personal Health Data

Increasingly more accessible via:

- Mobile apps,
- Wearable sensors,
- Social networks, and
- Other emerging technologies.

Need to optimize benefit and reduce potential harm risks.



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News Headlines



1:00 pm · Aug 10, 2018, 1:00 pm

Social Science One And How Top Journals View The Ethics Of Facebook Data Research

Ruben Leetaru

At a Big Data

Circle about the broad intersection of data and society



Facebook and Cambridge Analytica: What You Need to Know as Fallout Widens



The
Techlash
of 2018

TECH • ENCIPIR

Researchers Caused an Uproar By Publishing Data From 70,000 OkCupid Users



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Trust is Foundational



8% OF THOSE SURVEYED FROM THE GENERAL PUBLIC ACTUALLY TRUST TECHNOLOGY COMPANIES WITH THEIR HEALTHCARE DATA (GANDHI & WANG, 2015).



WHILE COMMERCIAL APPS OFFER READY TO USE TECHNOLOGY FOR HEALTH RESEARCHERS, THEY PRESENT CHALLENGES

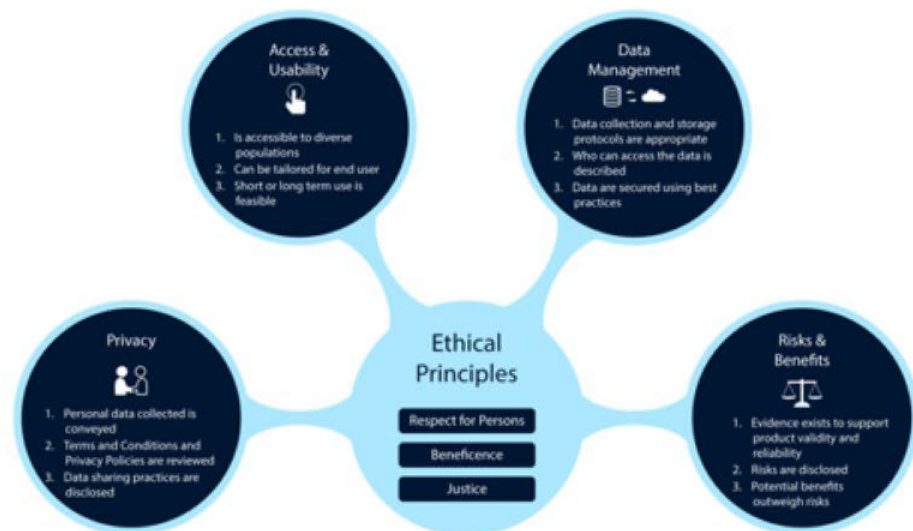
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Framework and Digital Health Checklist (DHC)



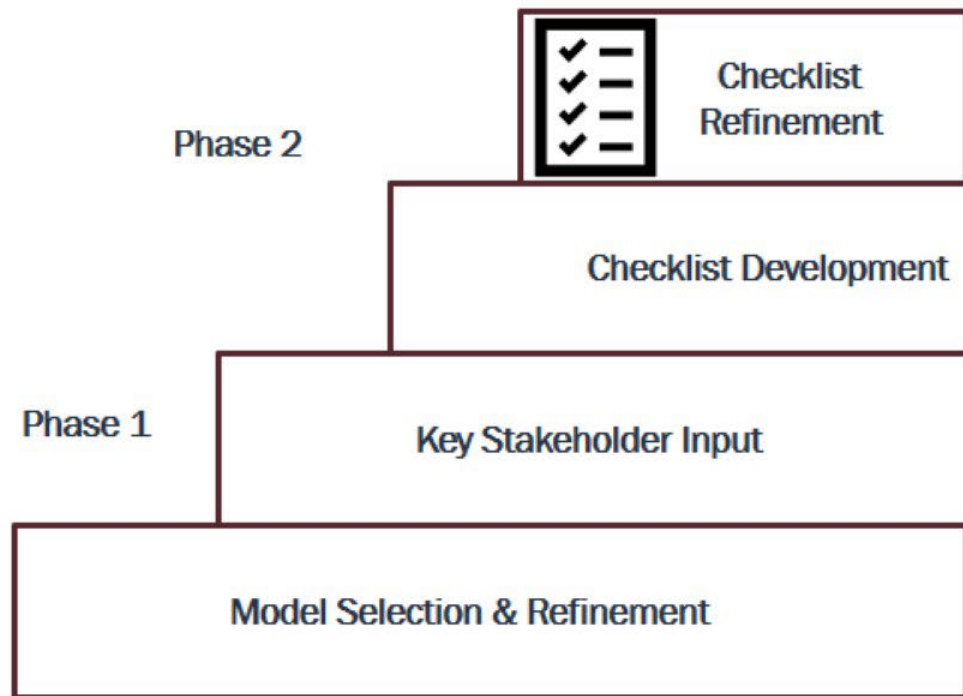
Domains	Ethical Principles Place a check to indicate the ethical principle(s) to consider for each item within a domain evaluated			Researcher Responsibility	
	<u>Autonomy</u> Actions demonstrate respect for the person	<u>Beneficence</u> Actions involve comprehensive risk and benefit assessment	<u>Justice</u> Actions demonstrate access to those who may benefit most	Addressed in the Research Protocol	Addressed during the Informed Consent Process
<ul style="list-style-type: none"> • Ethical Principles • Privacy • Risks & Benefits • Access & Usability • Data Management 					
Privacy (respect for participants)					
Personal information collected is clearly stated				Yes No Unsure	Yes No Unsure
What data are shared is specified				Yes No Unsure	Yes No Unsure
With whom data are shared is stated				Yes No	Yes No

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Iterative Approach to Develop the Framework and DHC



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Phase 1 Model Refinement

Purpose:

1. Determine if the modified American Psychiatric Association (APA) framework could be a useful tool for the digital health “research” ecosystem.
2. To confirm whether this framework was hierarchical

The American Psychiatric Association App Evaluation Model



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Ethical Principles Form the Foundation

- **Respect for Persons:** recognizes a persons right to make an informed decision
- **Beneficence:** reflects an obligation to carefully consider study risks and design the study to ensure social and scientific value
- **Justice:** emphasizes treating participants fairly and appropriate subject selection

The Belmont Report

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

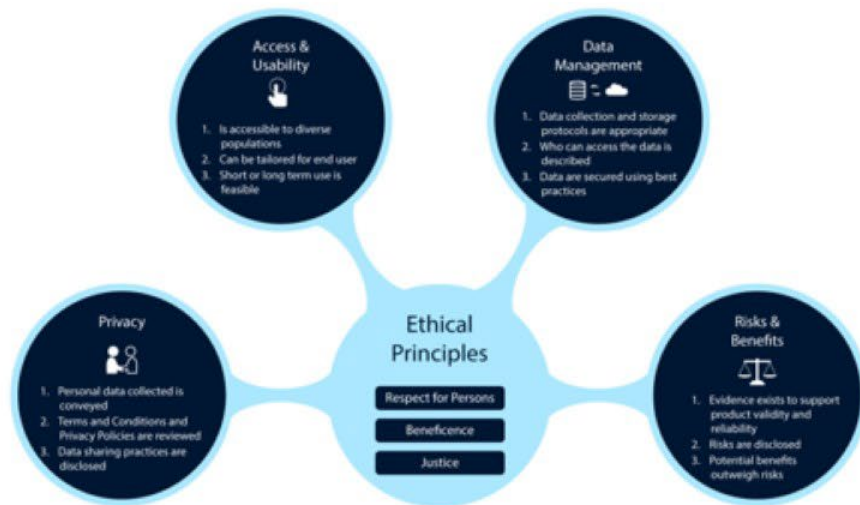
The National Commission
for the Protection of Human Subjects
of Biomedical and Behavioral
Research

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Factors Influencing Ethical Practice



(Nebeker, C., Bartlett Ellis, R. J., & Torous, J., 2020)

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Access and Usability

The domain of *access and usability* focuses on the design of the product:

- How it works
- How that is communicated to the user (informed consent or terms of service),
- Whether it's been used with the target population accessory tools that may be needed (smartphone, internet access),
- The extent to which the product can be used
 - ✓ both short and long-term.

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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?

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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?
- 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.

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Data Management

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?

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Use and Application of the DHC and Framework

- Research – designing, testing, data collection
- Practice/Institutions – Quality improvement initiatives, patient care
- Institutional Review Boards
- Technology Creators



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Key Takeaways

- Commercially available digital technologies are not regulated for application in all health contexts.
- Health care providers should consider the implications for patient access and usability, privacy, data management, and risks and benefits before recommending or adopting a digital technology for healthcare application
- The Digital Health Framework and Checklist can be used as a guide to help clinicians and others consider ethical aspects when selecting or recommending digital technologies for health application.

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Questions?

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 - c. Take the Posttest
5. After completing the posttest at 80% or above, your certificate will be available for print or download.
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