

# Research Ethics Cultivating Conversations Recap

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Digital Phenotyping in Psychiatry: Exploring Tensions between Privacy and Data Sharing Requirements

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The field of digital phenotyping in mental health research has gained attention in recent years. Digital phenotyping holds the potential to identify early at-risk individuals, enhance diagnostic accuracy, and improve treatment strategies through tracking and monitoring individuals' daily behaviors and disease progression. In addition to the advancements digital phenotyping offer, Dr. Raeanne Moore posed several ethical considerations and challenges researchers in this field may face.

This recap includes: (1) Summary, (2) Questions to Consider, (3) Resources.

Link to the [Zoom recording](#) to learn more about Dr. Moore's work.



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## Informed Consent, Data Confidentiality, and Participant Privacy

Digital phenotyping relies on users' ongoing willingness to grant access to sensitive personal health data, derived from devices like wearable sensors and smartphone applications. These devices gather data that can reveal an individual's daily activities and health-related information. Researchers need to ensure that participants are fully informed about the study, including the types of data to be collected and how that data will be used, shared and stored.

Certain sensitive data, like geolocation, can potentially lead to the identification of an individual when combined with other details within the dataset. While a person's step count or location may not seem concerning, these data are unique and pose a potential risk to participant privacy if data confidentiality is not maintained. This conversation underscores the importance of careful data management and privacy protection in digital phenotyping research.

## Ethical Questions to Consider:


1. How might we improve the process for enrolling participants to improve the likelihood that they are informed when agreeing to volunteer?
2. What can the Institutional Review Board or Library or Office of Research Administration do to support digital health researchers in designing appropriate data management plans?

## Data Sharing with Funders

The National Institute of Mental Health (NIMH) mandates that all funded projects report and submit their study data to advance research opportunities. This requirement can add a burdensome workload to the research teams. The research teams, in collaboration with NIH curators, create standardized templates for reporting data. Research teams need to carefully consider which data to upload to prevent any possibility of it being linked to specific individuals. This reporting process, while important, consumes a substantial

amount of time that could otherwise be allocated to conducting health research. Resources are needed to explore ways to minimize administrative burden and assist researchers to use their time efficiently throughout the reporting process.

### Legal/Regulatory Questions to

Consider: 

1. What is the institutional liability if the study data housed in the NIH repository is linked to a study participant?
2. What can the institution do to reduce data management burden that results from the NIH data sharing requirement?
3. What institutional resources are available to support researchers who need to comply such that the individual projects are not penalized?

### Recommended Tips and Resources to Conduct Responsible Digital Health Research

#### **Tip 1: Be transparent about goals and justification for data being collected to build trust**

-> Recruiting and Communicating with Research Participants – National Center for Complementary and Integrative Health

-> Sample Informed Consent Language Library (Describing technologies used in Research) – Harvard Clinical & Translational Science Center

#### **Tip 2: Communicate privacy and data security to participants**

-> Example of Stanford University Developed CARE-IT digital health app privacy policy

-> Nebeker, C., Gholami, M., Kareem, D., & Kim, E. (2021). Applying a digital health checklist and readability tools to improve informed consent for digital health research. *Frontiers in Digital Health*, 3, 690901. <https://doi.org/10.3389/fdgth.2021.690901>

#### **Tip 3: Ensure data encryption and anonymization**

-> Filkins, B. L., Kim, J. Y., Roberts, B., Armstrong, W., Miller, M. A., Hultner, M. L., Castillo, A. P., Ducom, J. C., Topol, E. J., & Steinhubl, S. R. (2016). Privacy and security in the era of digital health: what should translational researchers know and do about it? *American journal of translational research*, 8(3), 1560–1580.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4859641/>

-> Privacy Principles – American Medical Association (A case for privacy by design in app development)

-> Secondary Use of Data in Studies involving Wearable Technology – Harvard Clinical & Translational Science Center

#### **Tip 4: Design technologies to be convenient to users**

-> Noorbergen, T. J., Adam, M. T., Teubner, T., & Collins, C. E. (2021). Using co-design in mobile health system development: a qualitative study with experts in co-design and mobile health system development. *JMIR mHealth and uHealth*, 9(11), e27896.

-> Ray, J. M., Ratwani, R. M., Sinsky, C. A., Frankel, R. M., Friedberg, M. W., Powsner, S. M., Rosenthal, D. I., Wachter, R. M., & Melnick, E. R. (2019). Six habits of highly successful health information technology: powerful strategies for design and implementation. *Journal of the American Medical Informatics Association: JAMIA*, 26(10), 1109–1114.

<https://doi.org/10.1093/jamia/ocz098>

-> Issue Brief: Bridging the Digital Health Divide: How Designers Can Create More Inclusive Digital Health Tools – California Health Care Foundation

#### **Tip 5: Offer suitable financial compensation**

-> Bierer, B. E., White, S. A., Gelinias, L., & Strauss, D. H. (2021). Fair payment and just benefits to enhance diversity in clinical research. *Journal of clinical and translational science*, 5(1), e159.

<https://doi.org/10.1017/cts.2021.816>

-> U.S. Department of Health and Human Services. Addressing Ethical Concerns Offers of Payment to Research Participants.