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Some Privacy Issues in Unregulated Research Using Mobile Devices

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A. Some Legal Issues

1. If a state has a law regulating all research in the state (e.g., Md., Tex.), what law would apply where researchers are in one state and participants are in another?

    a. Researcher's state
    b. Participant's state
    c. State with most restrictive laws

2. If a state applied its own research law, would it also apply a Common Rule exemption adopted after the state enactment applying the Common Rule to all research within the state?

3. Common Rule Amendment (2018)

Secondary Research for Which Consent Is Not Required

This exemption at § ___.104(d)(4) is for secondary research uses of identifiable private information or identifiable biospecimens when consent is not required, if at least one of the following criteria is met:

. . .

- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).

  82 Fed. Reg. 7193 (2017).

Under the HIPAA Privacy Rule, consent or authorization is not required for uses and disclosures for “health care operations” or “public health.”

A HIPAA-compliant authorization is required for research with individually-identifiable health information

B. Ethical and Policy Issues

1. What harms are possible for privacy violations in the context of unregulated research using mobile devices?

   a. Physical harms caused by erroneous health information conveyed during research (e.g., ineffective or harmful meds)

   b. Dignitary and psychological harms caused by inadequate privacy protections or erroneous health risk assessments

   c. Economic harms caused by medical identity theft

   d. Societal harms caused by flawed research

2. What reasonable expectation of privacy does a participant in unregulated mobile health research have?

- It depends on the type of research

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Health Research Using Mobile Devices

	Research covered by Common Rule	Research **NOT** covered by Common Rule
Data gathered for research	Use of mHealth by traditional researchers	Citizen science Patient-directed research Independent research
Data **NOT** gathered for research	Conversion of clinical data for research	App developers, mHealth companies, or others

- Independent research, patient-enabled research, and citizen science research:

  Presumably, there will be some sort of permission sought before the participant agrees to provide information or otherwise participate.

  What elements of traditional research ethics should it include?

(1) Statement that it is research and the nature of research?

(2) Identity of researchers and sponsors?

(3) Risks and benefits, and nontherapeutic goal?

(4) Inclusion and exclusion criteria?

(5) No coercion or undue inducements?

(6) Protection for vulnerable subjects, e.g., children?

(7) Any costs to participants?

(8) Ability to withdraw?

(9) Disclosure of findings, return of individual results?

(10) No marketing?

- Research use of app data collected for another purpose

Does “click-through” consent give rise to a “reasonable” expectation of privacy?

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Regardless of the nature of the consent or the reasonableness of any expectations of the participant, is it reasonable to expect minimal protections when app-based health data are used for research?

If so, what should this include?

(1) Anonymity in reporting study results (?)
(2) No tertiary uses (?)
(3) Reasonable level of security (?)

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