The Common Rule & Research with Mobile Devices

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Outline

1. *When* is mHealth research covered by the CR (& what do we mean by "covered")?
    A. Is the actor covered?
    B. Is the activity covered?
2. *How* (well) does CR apply to mHealth research (when it applies)?
    A. Process
    B. Substance: risk-benefit analysis & informed consent
    C. Substantive gaps/failures of CR as it "covers" mHealth research
3. *What* should(n't) mHealth research governance borrow from the Common Rule?
    A. What (not) to steal
    B. Examples of CR adaptations applied to non-traditional research

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1. *When* does the Common Rule apply to mHealth?

When both (A) the actor *AND*
(B) the activity are covered

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A. Is the actor "covered"?

- Recipient of funds for HSR from CR agency/dept
- Affiliate of institution that has voluntarily promised to apply the CR to all HSR → RIP "checking the box"
- Affiliate of institution that applies the CR to some/all HSR as a matter of policy/employment contract
  - Virtually all academic institutions; some non-academic
- IF actor's institution is thereby "engaged in research"
  - Traditional researchers who collaborate w/non-traditional researchers thereby not always covered by CR
- Actor (and/or subject?) in state (e.g., MD) that applies CR to all HSR regardless of funding (enforced?)

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B. Assuming the actor is covered, is the activity "covered"?

Yes, if the activity constitutes "**research**" involving "**human subjects**" that is **not "exempt"**

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"Research"

"systematic investigation, including research development, testing, and evaluation, **designed** to develop or contribute to **generalizable knowledge**"

NOT research:

- Standard clinical care & innovative/untested care → CR can actually make it hard to achieve evidence-based practice & policy
- "pure" QI/QA (lots of corporate research could qualify)
- "public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority…necessary to…identify, monitor, assess, or investigate potential public health signals, onset of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products)"

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"Human subjects"

"a living individual about whom an investigator…:

(i) Obtains information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates **identifiable private information** or identifiable biospecimens."

- ***Private***: includes info about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and info provided for specific purposes by an individual that the individual can reasonably expect won't be made public (e.g., a medical record)
- ***Identifiable***: "identity of the subject is or may readily be ascertained by the investigator or associated with the information [or biospecimen]."
- **NEW**: Within 1 year & at least every 4 years thereafter:
  1. reconsider definition of "identifiable" → "if permitted by law," agencies may alter definition, including through guidance (*no* public notice & comment)
  2. consider whether some analytic techniques/technologies yield inherently "identifiable, private" data/biospecimen → add to list (public notice & comment) → agency guidance re: consent (*no* public notice & comment)

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"Human subjects"

Data collected via research app → covered through intervention &/or interaction with participants

Data collected for another purpose (clinical, administrative, or other research) → not covered unless BOTH private AND identifiable:

Private: how does "reasonable expectation" of privacy fit into mHealth & EULAs, etc.? Unlike FIPPS, no focus on context, only whether you expect data to be recorded (for any purpose).

Identifiable: "identity of the subject is or may readily be ascertained by the investigator"

- NIH recommendations to OHRP (Dec. 2001): "readily ascertainable" ≠ merely "possibly" ascertainable
- names & facial photos = ready ascertainment, but not associations w/other data that must be pieced together

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"Exempt"

- #2: Cognitive tests, surveys, observation of public behavior (including visual or auditory recording) IF:
  - data obtained is recorded by investigator so that subject identities can't be readily ascertained, directly or through identifiers linked to subjects OR
  - disclosure outside research team wouldn't reasonably put subjects at risk of liability or damage their financial, employability, educational, or reputational standing OR
  - data are identifiable but IRB conducts limited review of data privacy/confidentiality provisions (**NEW**; HHS guidance to come)
- #3 (**NEW**): Benign behavioral interventions with adults w/data collection through verbal or "written" responses or audiovisual recording IF consent &: [same three options as #2]
- #4: Secondary research w/identifiable, private data/biospecimens w/o consent IF: "publicly available" OR data recorded is non-identifiable (same as above) OR research regulated by HIPAA as "health care ops," "research," or "public health activities"
- #7&8 (**NEW**): Storage & analysis of identifiable private info/biospecimens w/broad consent IF: limited IRB review of proper broad consent +

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Summary: Not "covered" by the CR

1. All researchers on project are non-traditional
2. Non-traditional & traditional researchers collaborate, but latter's institution not "engaged in research"
3. Traditional researcher whose project isn't funded by CR agency (CR applies, if at all, by institutional policy → no different than #1 (e.g., MSR, FB, Fitbit), though longer tradition of applying CR)
4. QI/QA (not "research")
5. Use of existing (collected for clinical, operational, or other research purposes), non-"identifiable" data (no "human subjects")
6. Various exemptions (some of which require "limited IRB review")
7. Post-collection data sharing (or vending) → public sharing can feed into exemption 4 for "publicly available" (identifiable) data

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2. *How* does the Common Rule apply to mHealth research?

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A. Process

- Prospective IRB review of recruitment, consent materials/process (including documentation), protocol
- Approve, approve w/major or minor mods, disapprove
- Continuing review (less under revised CR)
- Most institutions (*not* CR) require IRB to determine whether proposed activity is non-HSR or exempt (but HHS planning decision tool to allow investigators to make exempt determinations)
- Expedited vs. full board review

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B. Substance: Risks & Benefits

- Standard: are research risks & (expected) benefits "reasonable"?
- Broad risks: physical, psychosocial, legal, economic, educational, reputational
- Narrow benefits to participants: direct, tangible, non-financial
- Undefined social benefits: importance of knowledge reasonably expected to result
- "The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy)"
- Risk minimization: no unnecessary risks; piggy-back on clinical procedures
- "When appropriate," ensure "adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data"

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B. Substance: Informed Consent

- Documentation of IC (unless waived) → digital okay
- Waiver/alteration: min risk + not practicable + not adversely affect rights/welfare + debriefing (as appropriate) → how do "rights" interact w/EULAs?
- Accessible language, opportunity to discuss & consider → lack of f2f consent?
- Minimize chance of undue influence → gamification?
- Elements: risks, expected benefits, alternatives, right to withdraw, extent of confidentiality
- **NEW**: For collection of identifiable data → statement whether it may be stripped of identifiers & used or shared for future research (or not)
- **NEW**: For biospecimens, statement may be used for commercial $ & whether participants will share in profits
- **NEW**: Broad consent (for storage & use of identifiable data/biospeciments):
  - "general description of types of research that may be conducted"
  - Which identifiable data may be used? Shared? W/what types of institutions/researchers?
  - How long will identifiable info be stored/used (can be indefinite)?
  - Statement they won't be told about each project & might not have consented to all
  - Unless known all individual, clinically relevant results will be returned, statement they may not
- **NEW**: must begin w/"concise & focused presentation of types information" most likely to help them understand why someone would/n't want to participate; "must be organized & presented in a way that facilitates comprehension" of info a "reasonable person" would want to know
- **NEW**: Must publicly post consent form for "clinical trials"

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C. CR Substantive Gaps/Failures

- Identifiable but not “private” data
- “identifiable” → “readily ascertainable”
- Identifiable but “publicly available”
- Silent on data sharing/vending
- Third-party & longterm social risks not to be considered
- Vague admonition re: data privacy/security
- Unhelpful, often unwarranted research/practice (including QI) distinction

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3. What should(n't) we borrow from the CR?

- Prospective group review, but…
  - IRBs are *differently* biased, not *un*biased
    - Bake outcomes measurement into research & review processes: continuous learning about research ethics, not just health
    - Rethink board composition or other ways to engage end users → correct curse of knowledge
  - Increase transparency (posting of "clinical trial" consent forms a small start)
- Risk-based: not-HSR, exempt HSR (w/ or w/o limited IRB review), expedited review, full board review
- Broad consent (but empirical work needed)
- Belmont principles are pretty good for general research:
  - Respect for persons → informed consent (but we don't do this well)
  - Beneficence → risk-benefit analysis (but this tends to be arbitrary & intuition-driven, not evidence-based)
  - Justice → equitable subject selection (but limited to participants; excludes other stakeholders)
- Recruitment/engagement, gamification, nudges & "undue influence" (please don't call it "coercion"!)
- Voluntariness: do some apps (e.g., FB) constitute monopolies?

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Examples of CR adaptations to non-traditional research we may want to consider…

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Washington and Lee Law Review Online

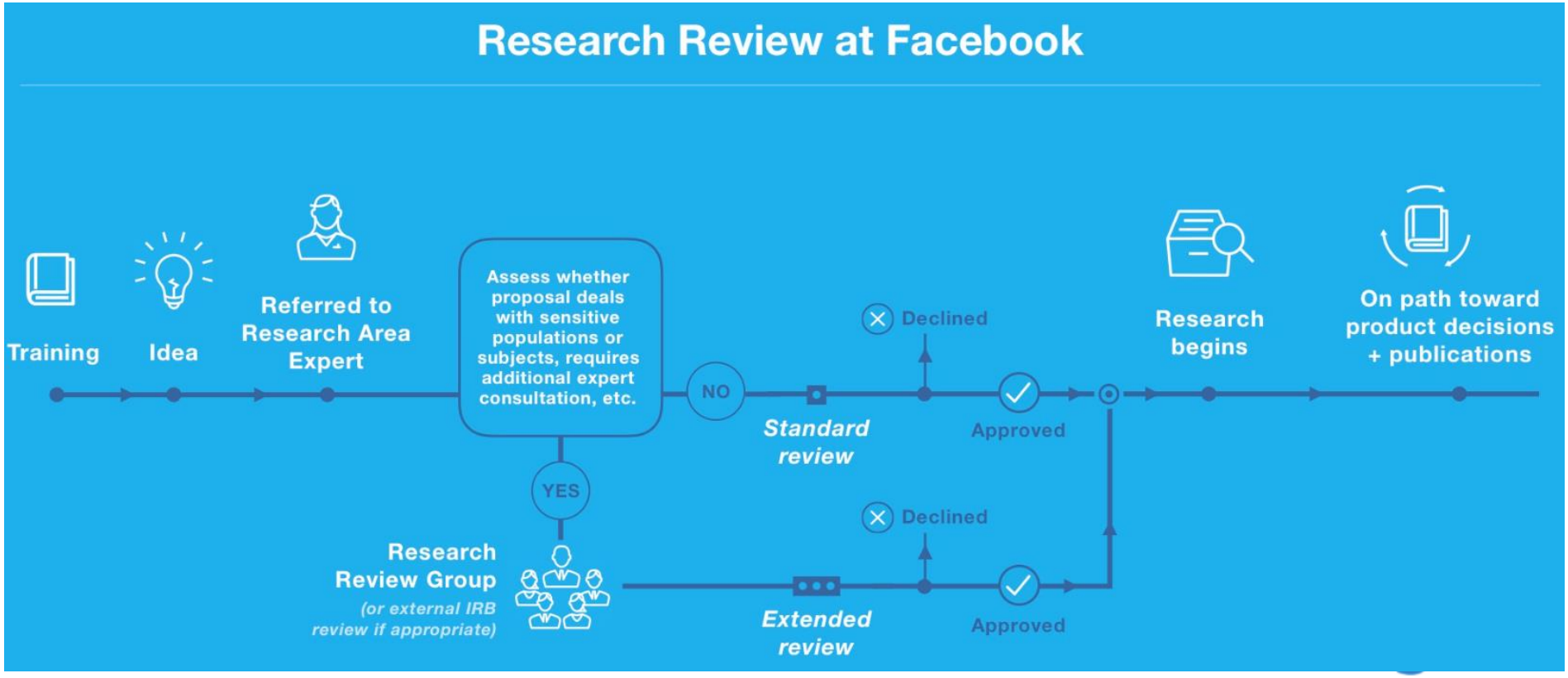
Volume 72 | Issue 3 Article 8

6-14-2016

Evolving the IRB: Building Robust Review for Industry Research

Molly Jackman
Facebook

Lauri Kanerva
Facebook



TOWARD PRIVACY AWARE RESEARCH AND DEVELOPMENT IN WEARABLE HEALTH

A report from the Center for Democracy & Technology and Fitbit, Inc.

By Michelle De Mooy & Shelten Yuen

fitbit

cdt

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CONSUMER DATA PRIVACY IN A NETWORKED WORLD:

A FRAMEWORK FOR PROTECTING PRIVACY AND PROMOTING INNOVATION IN THE GLOBAL DIGITAL ECONOMY

FEBRUARY 2012

THE WHITE HOUSE
WASHINGTON

ADMINISTRATION DISCUSSION DRAFT
CONSUMER PRIVACY BILL OF RIGHTS ACT

Bill

To establish baseline protections for individual privacy in the commercial arena and to foster timely, flexible implementations of these protections through enforceable codes of conduct developed by diverse stakeholders.

SEC. 1. Short Title. This Act may be cited as the Consumer Privacy Bill of Rights Act of 2015.

SEC. 2. Table of Contents.

SEC. 3. Findings. The Congress finds that:

(a) Americans cherish privacy as an element of their individual freedom.
(b) American laws, regulations, and enforcement entities provide robust privacy safeguards for consumers.
(c) There is rapid growth in the volume and variety of personal data being generated, collected, stored, and analyzed. This growth has the potential for great benefits to human knowledge, technological innovation, and economic growth, but also the potential to harm individual privacy and freedom.
(d) Laws must keep pace as technology and businesses practices evolve.
(e) Preserving individuals' trust and confidence that personal data will be protected appropriately, while supporting flexibility and the free flow of information, will promote continued innovation and economic growth in the networked economy.
(f) Enforcement of general principles in law will ensure that individuals continue to enjoy meaningful privacy protections while affording ample flexibility for technologies and business models to evolve.
(g) Enforceable codes of conduct developed through open, transparent processes will provide certainty for businesses and strong privacy protections for individuals.
(h) It is the sense of Congress that each covered entity should provide, when reasonable, a version of the notice required under this Act in a format that is computer-readable, to facilitate the development of information technology tools that will help individuals compare covered entities' personal data practices.

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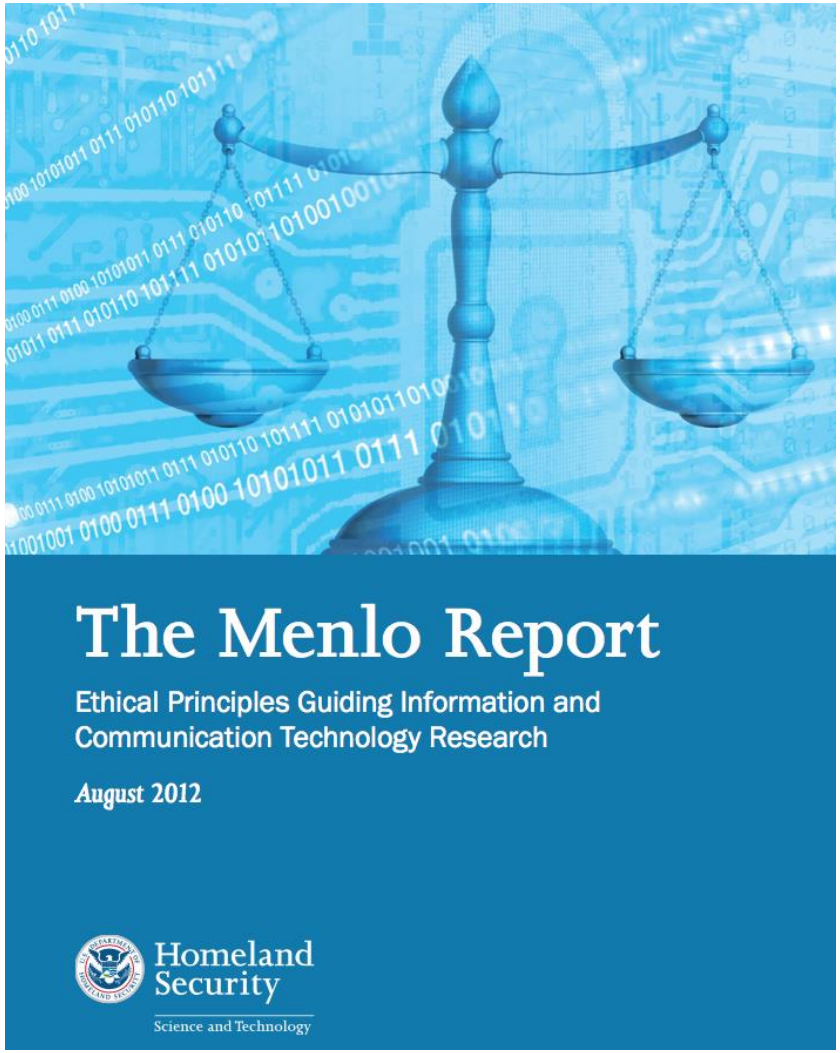

Applying Ethical Principles to Information and Communication Technology Research

A Companion to the Menlo Report

October 2013

Application of the Menlo Principles

C.1	Respect for Persons	
	C.1.1	Identification of Stakeholders
	C.1.2	Informed Consent
C.2	Beneficence	
	C.2.1	Identification of Potential Harms
	C.2.2	Identification of Potential Benefits
	C.2.3	Balancing Risks and Benefits
	C.2.4	Mitigation of Realized Harms
C.3	Justice	
	C.3.1	Fairness and Equity
C.4	Respect for Law and Public Interest	
	C.4.1	Compliance
	C.4.2	Transparency and Accountability

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Sage/Geisinger collaboration to compare standard consent to eConsent in an HER-enabled biobank

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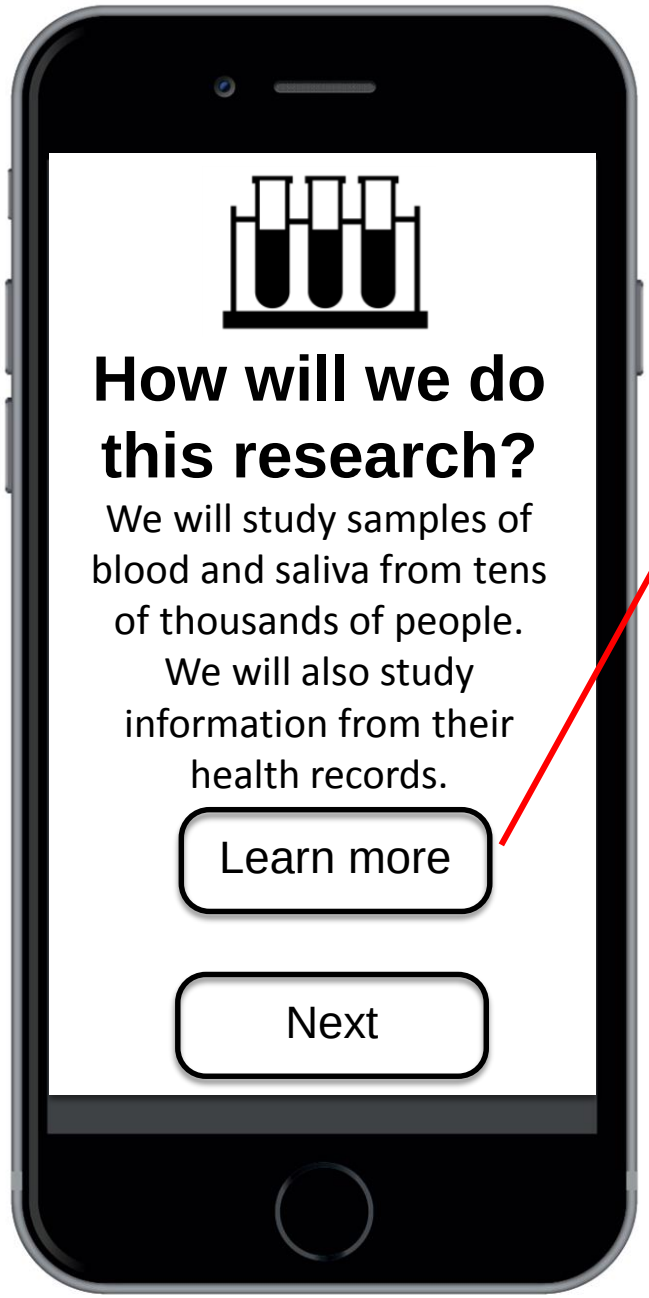

Learn more

We will collect samples of blood or saliva. We will store the samples in a biobank, which is a safe, secure place for storing samples.

We will use these samples for research studies.

We will collect information from Geisinger health records. This information might include the diseases people have, the medicines they take, and results of medical tests they get.

Many people are needed to do this research. We have samples and information from tens of thousands of Geisinger patients, and plan to collect more. Our goal is to enroll up to 500,000 Geisinger patients in this project.

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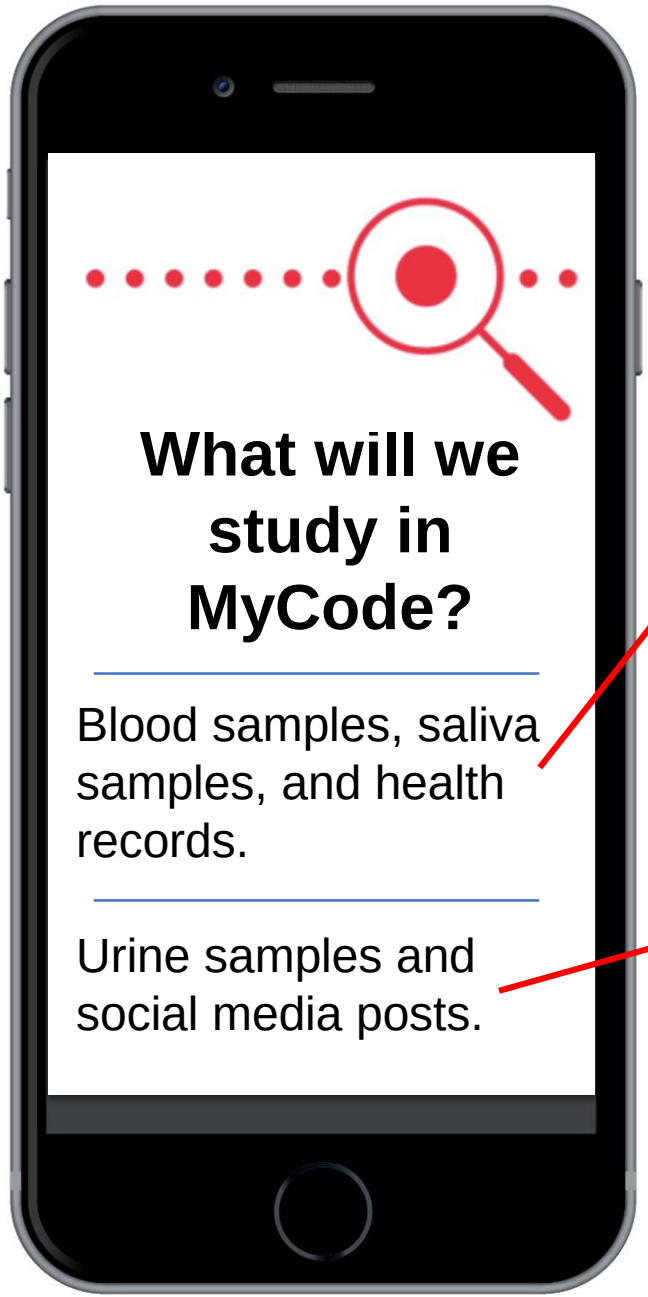

Correct!

We will study blood samples, saliva samples, and health records. We will study DNA in the blood and saliva samples. We will look for patterns in health records.

Got it!

Sorry, try again!

We will study blood samples, saliva samples, and health records. We will study DNA in the blood and saliva samples. We will look for patterns in health records.

Got it!

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“Clinical trial”

“a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes”

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