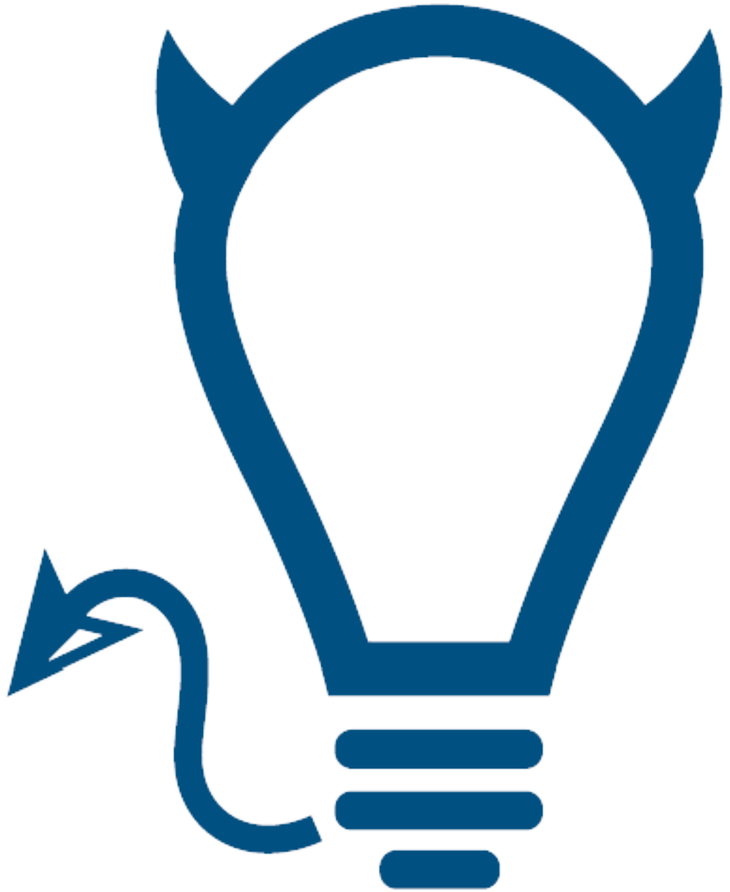

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Promoting transformative innovation in health and healthcare

Incubating Wicked Cool Ideas

Agenda

- What is Clinical Research?
- Applying Mobile Technology to Clinical Research / Healthcare
- Project Details

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Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people.

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Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people.

AWESOME, I NEED SOME GUINEA PIGS!!

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You cannot just decide to test a therapy or drug without a few things.

- A Principal Investigator
  - Someone that develops the research plan
- A Research Plan
  - Details about who to test, what you're testing, your expected outcome
- Approval from your IRB

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An institutional review board (IRB) is a type of committee used in research in the United States that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

Why do we have the IRB?

- The purpose of the IRB is to assure that appropriate steps are taken to protect the *rights* and *welfare* of humans participating as subjects in a research study.

Why do we have the IRB?

- Abuses and experimentations of persons without their consent.
  - Nazi Germany Concentration Camps
  - Tuskegee Syphilis Study

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The Tuskegee Study of Untreated Syphilis in the Negro Male, also known as the Tuskegee Syphilis Study or Tuskegee Syphilis Experiment was an infamous clinical study conducted between 1932 and 1972 by the *U.S. Public Health Service* studying the natural progression of untreated syphilis in rural African-American men in Alabama under the *guise* of receiving *free health care* from the United States government.

1932 - 1972

CFR 21 Part 11

- Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on *electronic records and electronic signatures* (ERES). Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records (Title 21 CFR Part 11 Section 11.1 (a))

Protected Health Information (PHI)

- Protected health information (PHI) under US law is any information about health status, provision of health care, or payment for health care that is created or collected by a "Covered Entity" (or a Business Associate of a Covered Entity), and can be linked to a specific individual. This is interpreted rather broadly and includes any part of a patient's medical record or payment history.

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Protected Health Information (PHI) 18 identifiers

- Names
- All geographical identifiers smaller than a state, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
- Dates (other than year) directly related to an individual
- Phone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health insurance beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Uniform Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger, retinal and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code except the unique code assigned by the investigator to code the data

Informed Consent (ICF)

- Informed consent is a process for getting permission *before* conducting a healthcare intervention on a person. A health care provider may ask a patient to consent to receive therapy before providing it, or a clinical researcher may ask a research participant before enrolling that person into a clinical trial. Informed consent is collected according to guidelines from the fields of medical ethics and research ethics. Overseen by the IRB.

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Let’s do a clinical trial !!!

Clinical Trial

- What are we studying?
  - Medication
  - Therapy
  - New use of an existing drug

Clinical Trial

- Who are we studying?
  - What is the patient population?
  - How many patients do you need to study it correctly?

Clinical Trial

- Who are we studying?
  - It would be ridiculous to study Inuit (Alaska) men and women ages 18 to 30 in the city of Durham.
  - It would be ridiculous to study women ages 75 - 99 who are pregnant.
- We have to be clear in our patient population.

Clinical Trial

- Studying the use of Drug A on men and women ages 18 - 29 who are US citizens, can speak english and have an allergy to cats.

Clinical Trial

- Studying the use of Drug A on men and women ages 18 - 29 who are US citizens, can speak english and have an allergy to cats. This is known as Inclusion/Exclusion Criteria.

- How can you test if your theory is valid?

  - You are giving Drug A to everyone in the study!!

Clinical Trial

- Patient Groups
  - Control - they do not get Drug A or get a placebo
  - Intervention - they get Drug A

Clinical Trial

- What are we going to give the patients for participation?

Clinical Trial

- What are we going to give the patients for participation?
  - Nothing?
  - Gift Cards?
  - Money?
  - Free care during the trial?
- We can give them all the above.

Clinical Trial

- We are going to give Patients money. $25 every appointment they attend for us to gather blood samples and check their allergy levels.

- What if they decide not to continue with the study?

  - They pay the money back? NO!

Clinical Trial

- Patients are free to withdraw from the study at any time without personal liability.
  - We don’t want patients to be coerced into participation and feel they are obligated to continue.
  - They just won't get paid going forward.

Clinical Trial

- If there happens to be an averse event during the trial - such as a patient dies <u>as a result of the study</u>.
  - The study may be stopped.
  - All patients must be notified and given the choice to continue or withdraw from the study.

Clinical Trial

- To explain all this to the patient we need to get their Informed Consent Form (ICF) signed.
    - This form *should* be written at an 8th grade level so it is easy to understand. Videos are used for this process and digital or ink signatures are gathered.

Clinical Trial

- We have the Informed Consent Forms and now the patients are called Study Participants.

Clinical Trial

- We may partner with many Sites across the United Stated.
  - A Site is another medical institution, with an IRB, that has been given the permission to collaborate with us to gather diverse patient populations.

Clinical Trial

- We need to create
  - A website to notify patients.
  - A paper log or journal for all their allergic responses.
  - Flyers to get patients to enroll.
  - Paper documents that will explain the medications and elements of the study.
  - Informed Consent Forms for the patients to sign
- We need to do this for every site participating

Clinical Trial

- Gathering Data
  - We have to communicate with the sites to get the data from all patients to do analysis on the results.
- If only there was a way to reach a lot of patients all over the country/world. Enroll them, consent them and start gathering data that will be sent back to our site.

Questions?

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Almost everything will work again if you unplug it for a few minutes… including you.

Anne Lamott

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Using Mobile Technology with a Clinical Study

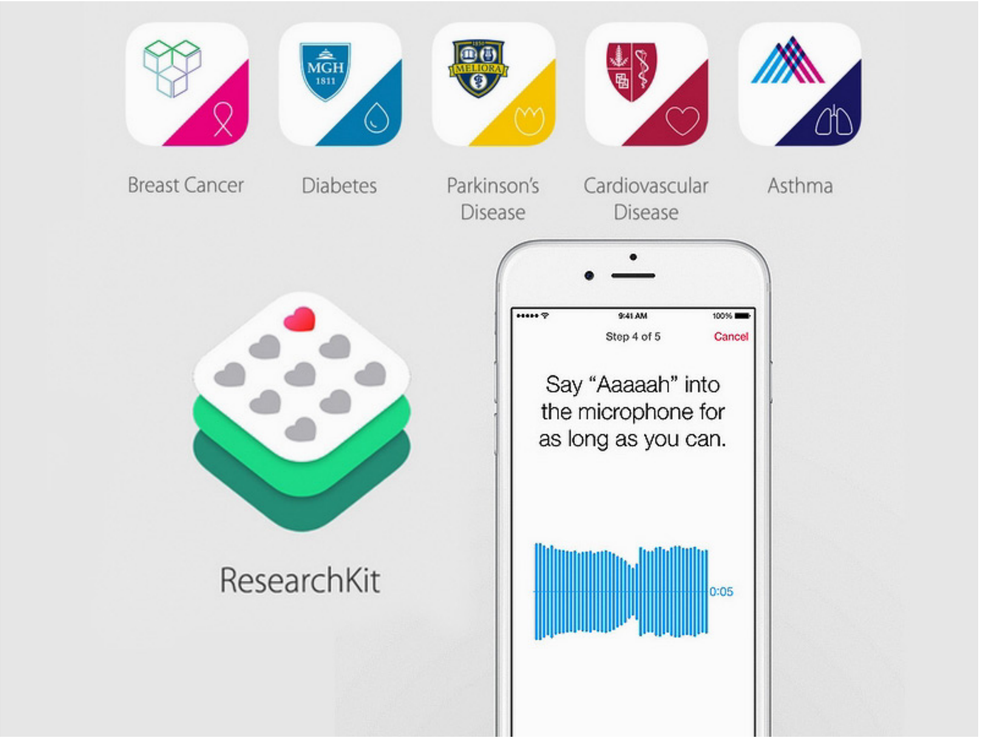
We have technologies that make it easier to reach patients all over the country.

Instead of reaching 200 participants, we can now reach 2000 or more depending on the study.

Apple created ResearchKit for the iOS platform.

It allows us to do all the functions we learned about earlier.

- Informed Consent
- Inclusion/Exclusion
- Allowing patients to withdraw
- Gathering data



There is also ResearchStack for the Android platform.

It also allows us to do all the functions we learned about earlier.

- Informed Consent
- Inclusion/Exclusion
- Allowing patients to withdraw
- Gathering data

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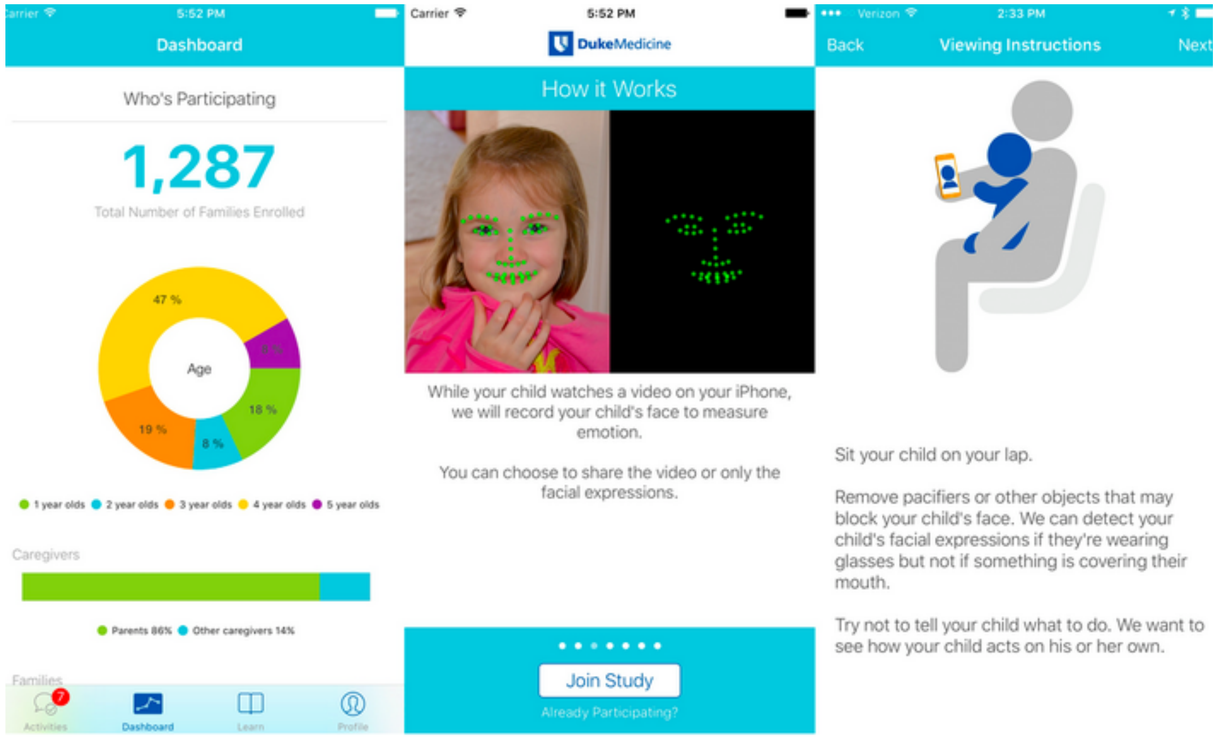
DIHI was one of the first 6 ResearchKit apps in the AppStore with Autism and Beyond.

Autism and Beyond used facial recognition to detect autism in young children.

This would not have been possible without using mobile technology available today.



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DIHI is currently working on Cancer Distress Coach for both Android and iOS.

Cancer Distress Coach helps cancer patients and survivors cope with symptoms of PTSD related to cancer diagnosis and treatment.

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Technology available today allows us, as developers, to write applications that are more personal to the patient.

The patient has tools in their pocket that before was only available in clinic.

Because of the intimate and personal bond people have with their phone, we can leverage that to get more people involved in studies.

Of course we cannot lose sight of the real reason we write apps for patients and physicians.

To better care, communicate and involve the patients in better quality healthcare.

Patients first.

Things we have to be cautious of:

- Do not write apps that *diagnose and give treatments or medication dosages* for a medical issue. These are not apps, but devices in the eyes of the FDA.
- Do not gather data about the patient (text messages, photos, music preferences) without getting their informed consent first.
- NEVER write an app unless you have gotten approval from the IRB for the trial/study.

For instance:

A study was being conducted, without permission from the IRB. The study was to detect frequency, type and content of text messages and emails sent and recieved by teenagers (13 - 15).

To do this, the teenagers were given a jailbroken phone that allowed root access by the tech group assisting with the study.

Why is this a bad idea?

Information about the teenagers geolocation, email accounts, passwords, text messages, photos and other identifiable information was being sent back to the group running the trial.

Just for your information - it is a felony to have pictures of underage persons (child pornography) on your computer. It is punishable by imprisonment and registering as a sex offender in some jurisdictions.

What do you think teens are texting each other?

What do you think teens are sending pictures of to each other?

This is why we have protocols in place to protect patients rights…

And to protect the investigators from mistakenly doing anything that violates local, state and federal laws or regulations.

Questions?

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Lets create our own mock clinical trial using mobile technology.

Don’t panic!

We’re all in this together.

Our clinical trial will study favorite ice creams and snacks of participants.

We will not provide snacks and ice cream.

We are studying men and women ages 18-25 that do not have any lactose intolerance or allergies. They must be able to read and write English and be a US citizen.

Consent the patient to participate in the study.

Create an account (mock)

Surveys or questions we will ask are:

- Favorite flavor of ice cream given 4 choices. Select one.
- Favorite snacks given a list of 8. Select multiple.
- Ask them to give in a short text answer why they like the ice cream or snacks they selected. (This is a follow-on question to the surveys).

Show how to get the results from the surveys. (print to console?)

You may work in teams or by yourself.

All work must be put in gitlab.

Next week we will have a demo of your work.

Thank you.

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