How to Review Online Research

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Disclosure

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

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Online Research Ethical Challenges

- **Recruitment**
- **Informed Consent**
- **Privacy and Confidentiality**
- **Justice**
- ***Data Validity***

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Online Research Ethics Considerations

- **Recruitment**
  - When does research begin? Are we giving marketing companies information about people who click our research ads?
- **Autonomy: eConsent**
  - Tech can help us do this better
- **Risk Benefit determination**
  - **New or Different risks**?
  - **Magnitude of Risks**?

    Are some of the risks, which historically are considered minimal now greater than minimal?
- **Justice considerations:**
  - Who doesn't have access? (platform specific?)

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Online Recruitment Uniqueness

- **With Online Behavioral advertising tools:**

20-30 years old

PENN

Morgan Stanley

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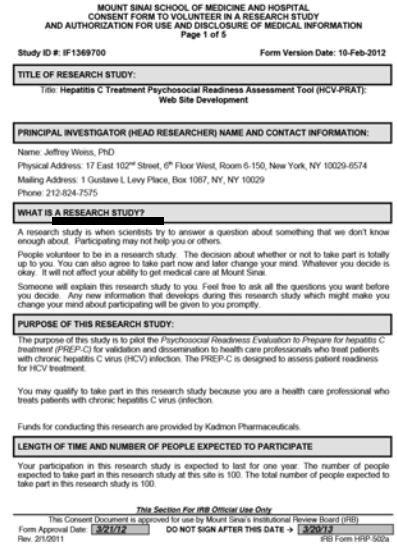
Traditional research consent



MOUNT SINAI SCHOOL OF MEDICINE AND HOSPITAL
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Page 1 of 5

Study ID #: IF1369700 Form Version Date: 10-Feb-2012

TITLE OF RESEARCH STUDY:

Title: Hepatitis C Treatment Psychosocial Readiness Assessment Tool (HCV-PRAT): Web Site Development

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Jeffrey Weiss, PhD

Physical Address: 17 East 102nd Street, 6th Floor West, Room 6-150, New York, NY 10029-6574

Mailing Address: 1 Gustave L Levy Place, Box 1087, NY, NY 10029

Phone: 212-824-7575

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care at Mount Sinai.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study which might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to pilot the *Psychosocial Readiness Evaluation to Prepare for hepatitis C treatment (PREP-C)* for validation and dissemination to health care professionals who treat patients with chronic hepatitis C virus (HCV) infection. The PREP-C is designed to assess patient readiness for HCV treatment.

You may qualify to take part in this research study because you are a health care professional who treats patients with chronic hepatitis C virus (infection.

Funds for conducting this research are provided by Kadmon Pharmaceuticals.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last for one year. The number of people expected to take part in this research study at this site is 100. The total number of people expected to take part in this research study is 100.

This Section For IRB Official Use Only

This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)

Form Approval Date: 3/21/12 DO NOT SIGN AFTER THIS DATE → 3/20/13

Rev. 2/1/2011 IRB Form HRP-502a

Traditional boilerplate informed consent forms meet regulatory requirements but complexity and legal document format inhibit understanding

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Informed Consent Recommendations

Strick a balance between presenting enough information to participants but not too much…

1-2 paragraphs on data security

vs

1-2 pages on data security

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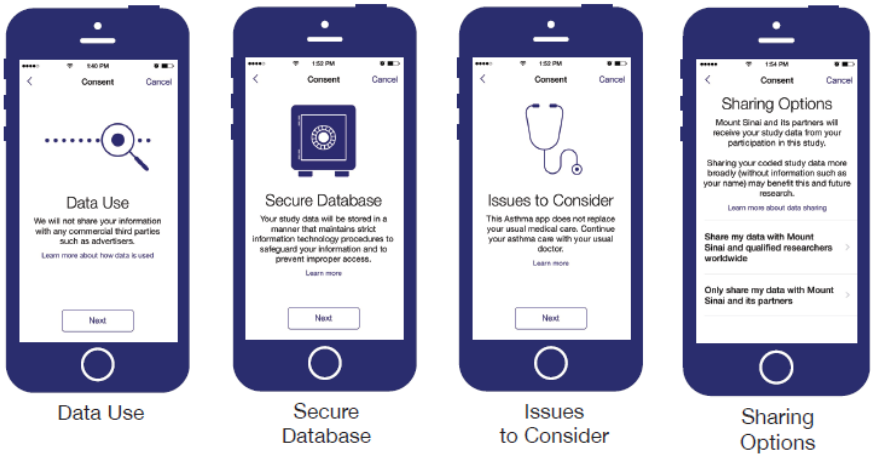
Iconic interfaces with layered information



Data Use | Secure Database | Issues to Consider | Sharing Options

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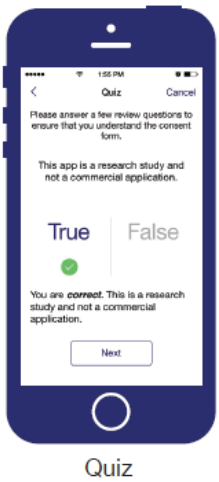
Discussion & Comprehension



Quiz

- **Informed consent discussion with investigator is considered the cornerstone of informed consent**
- **Test of understanding of main issues highlighted in iconic interfaces**
- **Can request phone or email contact for questions, verbal discussion**

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A Better Consent Process?

Multi-modal consenting; using visual (charts, graphics, videos), and written consenting that includes interactivity (quizzes, check-boxes, discussions etc.) in e-consenting platforms.

The Block Rule: the use of three different modalities to adequately ensure that subjects understand and comprehend the study is likely enough to meet the regulatory criteria for informed consent.

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EULAS vs. Consents

Consent is a process, not a click-box

EULA: The End User Licensing Agreement

- long legalistic language in tiny print that the user simply clicks accept to without usually reading.
- *The word "research" is usually buried somewhere in there…*

Research consents may contradict EULAS. It's important to review the EULA but is it necessary for researchers to abide by it? (you may want to refer to the institution's legal department)

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Risk | Benefit

Privacy / confidentiality (GPS data, IP addresses, location-based services). *Much of this is directly tied to the technology itself.*

Collecting information from or about bystanders. What data types or activities are more likely to have this occur? Some interesting technology can help with this.

Consent legitimacy: can you verify the person using it is the person you think they are and is appropriate to be in the study? What technical solutions can accomplish this verification?

Risk | Benefit

Hawthorne: Participants may be self-conscious about giving constant information.

Anti-Hawthorne: Participants might become so accustomed to being monitored/giving information that they forget about, resulting in giving information they wouldn't otherwise want to share.

Efficiency of technology: efficiently diffusing non-compliance! More efficient process could mean that errors spread more efficiently.

And, how do we examine the risk of "the cloud"?

Risk | Benefit and Vulnerable Populations

Group

- **Children – tech adoption higher, generational knowledge of risks shows big differences**
  - Cyber-bullying
  - Sharing practices very different

- **Prisoners – generally they have extreme limitations of access to technology**

Situational

- **School environment**
- **Catastrophes & Disasters**
- **What are public and private spaces "digitally"**

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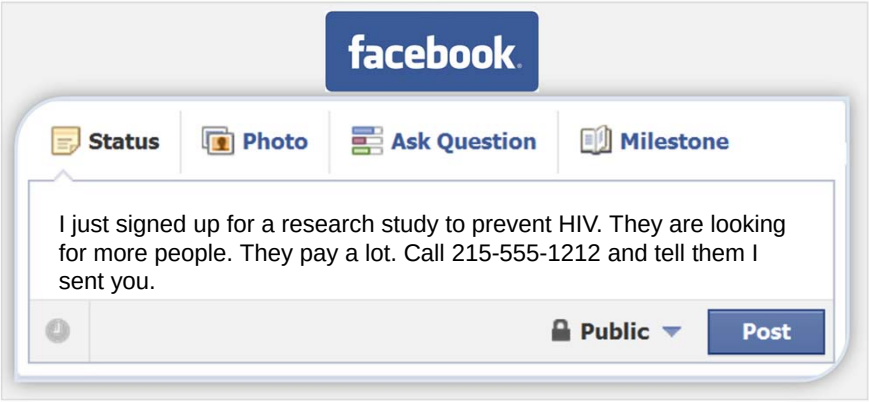
Participants Identify Themselves



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Justice Considerations

The Good:

- Access to research greatly improves
  - For participants!
  - For researchers!

The Challenge ?

- Access biased towards adopters (unless you provide them with the device)
  - Allows the most vulnerable and underserved to participate

Data Validity

What protocols exist to ensure submissions are valid?

What protocols exist to ensure the validity of participant responses?

Compliance Protocol Design

- Describe in tabular and graphical the data
- Provide a schematic of the underlying logic of the platform
- Make a distinction between what's *novel* technology vs. what is using technology to do something that has been done before
- Rethink the risks, including situational risks based on a reasonable prediction of how/when/where the app will be used

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Compliance Protocol Design

	Who?	What?	Where?	When?	Why?	How?
Data Type	Entered by subject? Auto-collected by device/ platform?	PHI? Survey? GPS? Interaction or usage of device/ platform?	Under what circumstances or situation will it be entered?	By user action? By device/ platform?	Primary data for the study? Data about the device/ platform itself?	What is the detailed mechanism for collecting this?

Investigators and developers should map out all the data collection, and sharing points along with descriptions of the security measures and how it protects the privacy of the subjects

This will go a very long way in terms of explaining the more complicated workings of the applications researchers develop and seek to use

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Compliance Protocol Design

- It's hard to tell in these systems without really being methodical if it meets all the criteria
- Creating massively efficient systems using technology means you can *create massively efficient non-compliance!*
- Jurisdiction and applicability of laws: foreign countries, different laws by region or municipality etc.
- Bad actors, cybersecurity threats etc.

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Questions to ask

"A prudent question is one-half of wisdom."

— Francis Bacon

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Important Questions

- **Where do the interactions, communications, and study take place?**
- **What ethical expectations are established by that venue?**

The greater the perceived privacy of the participant and/or the less privacy afforded by the venue, the greater the need to protect individual privacy, confidentiality, and right to informed consent

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Important Questions

- **Who are the participants?**

The greater the vulnerability of the participant, the greater our obligation is to protect the participant.

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Important Questions

- **When will the informed consent process start?**

Ideally, protecting participants' rights to privacy, confidentiality, autonomy, and informed consent should start at the beginning of any data collection.

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Important Questions

- **How long does the third-party provider preserve the data and where?**

Every effort should be made to (a) not store data by third-party providers and (b) if it is being stored, have the data removed as soon as possible.

Researchers need IP addresses to ensure the integrity of the date being collected.

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Important Questions

- **What third-party policies impact the research?**

Have general counsel review the terms and services of the sites and any third-party provider contracts. The researcher should provide adequate information to participants and ethic review boards concerning how third parties will protect the data.

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Handout Discussion

Electronic Data Security

Data management of human subjects research data includes: data collection, data entry, and database repository oversight (controlling access, tracking use of analytic datasets). When reviewing electronic data collection, there are 4 important areas to examine:

Identifiers 1

- What type of identifying information will be collected?

Technologies 2

- What types of technologies will be used in the research study?

Data 3

- Once data is collected, how will it be transmitted, processed, and stored?

Security 4

- During data collection, how will it be transmitted, processed, and stored?

1. Identifiers

Anonymous data – at no time will any identifiers be collected including IP addresses?
If these identifiers are being collected, a data security review is recommended:

- Name
- Device identifiers/serial
- Account numbers

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1. Identifiers

Anonymous data – at no time will any identifiers be collected including IP addresses?
If these identifiers are being collected, a data security review is recommended:

- Name
- Electronic mail address
- Social security number
- Telephone number
- Fax number
- Internet protocol (IP) address
- Device identifiers/serial numbers
- Biometric identifiers
- Images (face)
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Medical record number

2. Technologies

What types of technologies will be used in the research study?
Cellphone app, wearable device, text messaging, web-site, web-survey, electronic recording, and or video?

- Who developed the platform?
- How will it be accessed?
- How will the data be stored?
- How is the data coded?
- Where is the site/data hosted?
- Security features of the platform? (ex: password protected, encrypted during transmission)
- Will GPS data be collected?
- Can users turn GPS off?
- Is the communication one-way or two-way?

3. Data

Once data is collected, how will it be transmitted, processed, and stored?

- Who owns the server? Server operating system?
- Will cloud file storage be used?
- Will data live on a workstation? Laptop?
- Where will the data be housed?

4. Security

During data collection, how will it be transmitted, processed, and stored?

- Who will have access to the data?
- How will data access be managed?
- Who is responsible for maintaining the security of the data?

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Case Study 1

Predicting AOD Relapse and Treatment Completion from Social Media Use

- Recruiting adult participants attending outpatient drug treatment
  - some of the participants are ordered by the court to attend treatment
- Hired a company to collect their social media data from when they opened their account until 26 weeks from starting treatment
  - Images, videos, post, private messages, etc
  - Content is timestamped and link to accounts of others on the social media platform
  - Able to merge data from all of their SM accounts and Browser searches
- Weekly text messages ask participants if they relapsed and to provide information about which drugs they used in the last week

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This is an example…I am not doing this in my study

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Case Study 2

HIV Testing and Condom Use Reminder Service

- Population: Youth who are at greater risk for HIV infection
- Text messaging study that uses location information
- Participants are reminded to get an HIV/STI test periodically or if they are near a free HIV/STI testing location
- Weekly survey regarding sexual and AOD activity

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Case Study 3

Smartphone & Alcohol Breathalyzer Study

- One of the inclusion criteria is having reported driving while intoxicated in the last 30 days.
- Participants blow into a breathalyzer that sends a record of their blood alcohol level.
- While using the device, a timestamped video is recorded and retained on their phone.
- Participants do this 5 times a day (during typically “drinking” hours)
- If they blow above the legal limit, a message appears on the phone asking them if they would like to have a free ride home
- Data is stored on the phone and in the cloud

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ANY QUESTIONS?

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