Strategies to Promote Ethical Practices in Research:
Potential risk and ethical dilemmas in digital research

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Case Study

Study Objective

To optimize and evaluate reliability and acceptability of a new smart phone-connected, wrist wearable device to monitor falls among older adults, in real-world settings.

Randomized comparison to “standard” landline connected device worn around neck.

Study Personnel/Roles

- Collaboration between JH Medicine investigators, JHU Biomedical Engineering investigators, and external digital health company
  - **JHM** team to interact primarily with patients
  - **BME** team to interact primarily with digital health company to optimize platform and device
  - **Digital health** company to provide device/platform, and serve as data intermediary

Study Population/Recruitment

- Women and men 65+ who:
  - Have a smartphone with data plan
  - Willing to wear device around wrist that communicates with mobile phone

  OR
  - Have landline
  - Willing to wear device around neck that communicates with landline

- Participants are JHMI patients recruited via email, patient portal, clinic flyers, and through primary care providers

Consent

- Study team proposed to use eConsent approach
- Link to consent platform sent to potential participants via email

Devices

- Wearable device containing sensors designed to detect falls
- Device communicates with phone and synchronizes with mobile app
- App automatically launches when phone boots up; does not transmit when phone is off. Possible to enable/disable fall detection within app
- Provides location, date, time and intensity (g-force) of fall. Device also detects and sends heart rate before, during and after falls.
- Monthly cost ($25) covered by research study for period of the study

- Comparison to land-line based fall detection medical alert device worn around neck

Data

- Fall information and heart rate data transmitted to digital health company and recorded in database
- Patient can add other individuals to receive alerts via SMS and/or email, if desired
- Audible alarm and light on phone when fall detected. Countdown timer allows wearer to cancel transmission of an event alert within 30 seconds of fall to minimize risk of transmitting false data
- Identifiable device data (linked to phone numbers/user profiles) collected by 3rd party digital health company
- User experience surveys also completed online and sent to 3rd party vendor
- De-identified data provided to JHU team
- JH Medicine and BME teams will together analyze all data

A Twist…

After several months of enrollment, JHU PI is recruited to different institution and plans to take study and data with her

What ARE the Risks?

- **Data Loss/Breach of Confidentiality of Participants**
  - Risk increases when data is shared with external partners
  - How secure is the device/platform? How secure is transmission of the data through the platform? How will online surveys be collected?

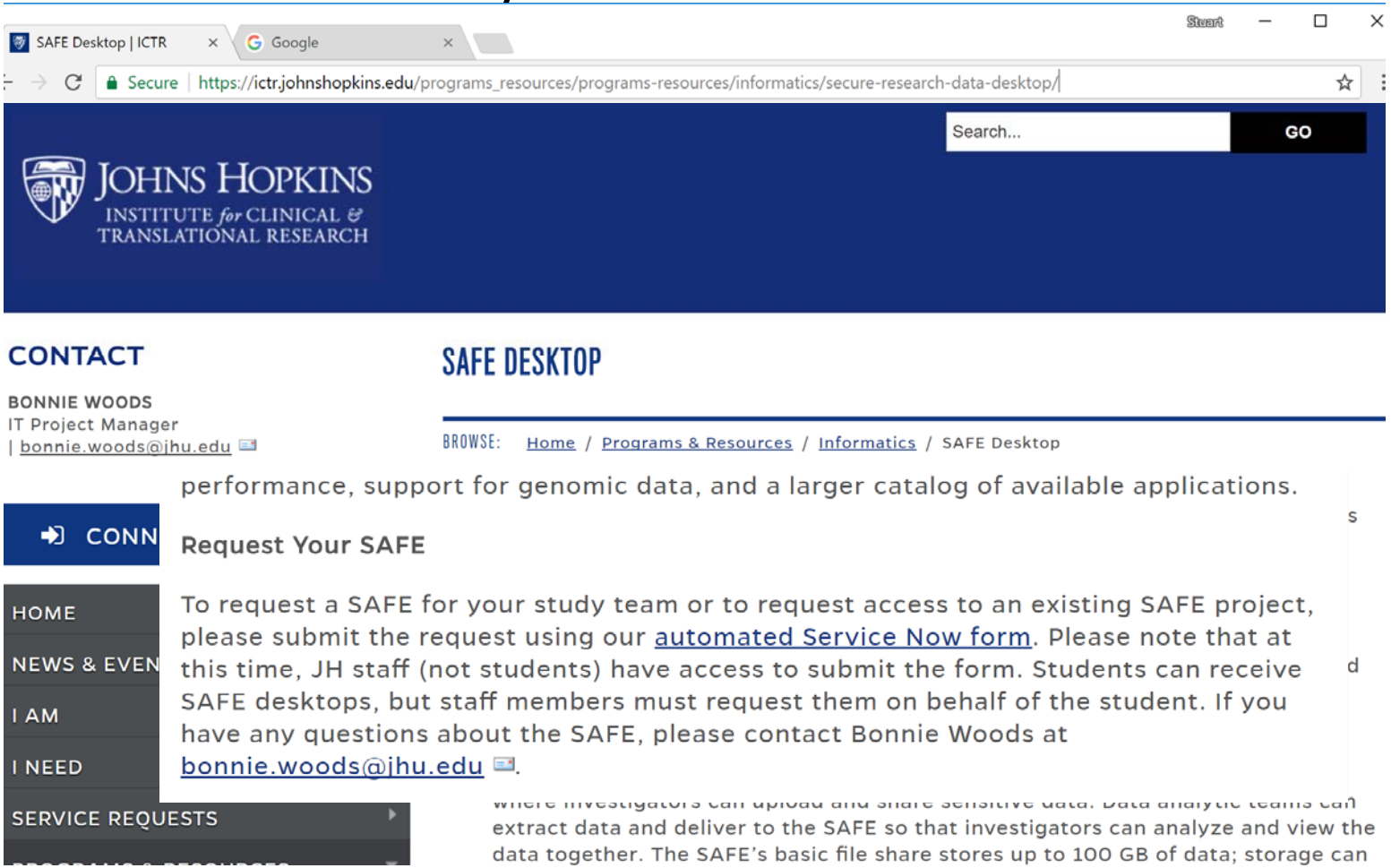
- **Risk that the device/alert system will not work or may not work effectively [It is still being investigated!]**
  - Possible risk that the device will send erroneous messages/alerts
    - Could that information be used to treat patients in error?
  - Possible risk that the device could have unknown risks
    - Is there a consequence of the notification/alarm for subjects?
  - Is sending of alert information to the 3rd party device company a sufficient "monitoring" strategy? Do they have the clinical expertise to follow-up?
  - How are third parties notified if they have been "signed up" to receive alerts? What is their responsibility?

- **Risk that eConsent may not be effectively obtained in the targeted population**
  - Is the elderly adult population able to provide consent/understand study obligations where e-consent is used?

Regulatory Considerations

- **FDA Regulations:**
  - The wearable device may qualify as a medical device subject to FDA regulations
  - If an FDA-regulated medical device the researcher will need to understand whether the risk posed qualifies as a significant/non-significant risk
- **HIPAA:**
  - Patient data shared with BME and Digital Health
    - Both are NOT part of the covered entity
  - Some elements of the data to be shared may constitute PHI [Need subject authorization or waiver to share the data]
  - May require appropriate agreements to permit sharing [DUA, BAA]
  - Breach implications
- **E-Consent**
  - Regulations permit use of e-consent where documentation of consent can be waived [Study must be minimal risk]
  - If the study poses greater than minimal risk AND is FDA-regulated, additional requirements exist for signature validation

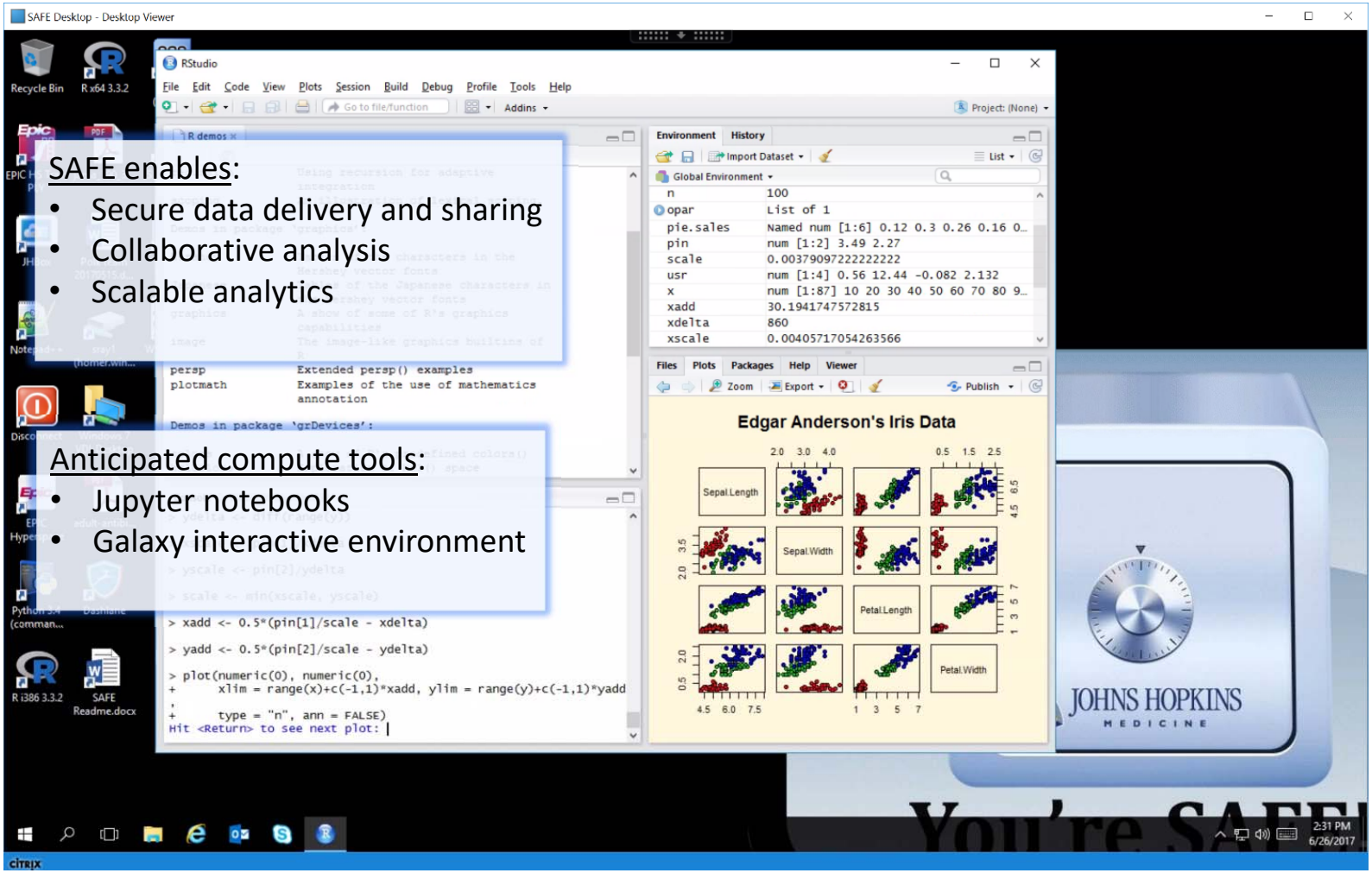
Secure Analytic Framework Environment (SAFE)



https://ictr.johnshopkins.edu/programs_resources/programs-resources/informatics/secure-research-data-desktop/

Or, just Google:
"johns hopkins safe desktop"

SAFE Desktop



Intranet Site

http://intranet.insidehopkinsmedicine.org/data_trust/index.html

Research Data SubCouncil Review Examples

Criteria	Review required
Data are being transferred outside of Johns Hopkins to a government agency or a contractor working on behalf of a government agency, and data transfer is required by the grant.	• Research Data Sub-council co-chair review • Chief Information Security Officer (CISO) review of data security measures
Data will reside on a Johns Hopkins system other than JHBox, and non-JH research partners will have access to the Data. Researchers are working with CCDA and IT@JH to implement appropriate security measures.	• Research Data Sub-council review, PI participation not required
Data request is unusually large (>499)	• Research Data Sub-council review
Data are being transferred outside of Johns Hopkins to a research partner.	• Research Data Sub-council review

FAQ: http://intranet.insidehopkinsmedicine.org/data_trust/research-data-requests.html

Data Integrity

Secure the data with which we've been entrusted

- Portable devices must be password-protected and encrypted!

Protect data from loss

- Valuable data should reside on JH network storage (IT@JH/LAN-managed)

Maintain data to establish validity and enhance reproducibility

- All research data should be collected, stored, and retained in a manner that supports **curation** and **provenance**

Responsible data sharing is compatible with the above, but a separate topic

Data Curation and Provenance

- the selection, preservation, maintenance, collection, and archiving of data assets
- establishes, maintains and adds value to repositories of digital data for present and future use
- a core competency for researchers

Can we answer these questions about each publication?

- Where are the primary data?
- By what processes did they arrive in their current state?
- Who changed them along the way?
- How were figures and tables generated from those data?

prov·e·nance (prävənəns) *noun*
the place of origin or earliest known history of something.

- the beginning of something's existence; something's origin.
- a record of ownership of a work of art or an antique, used as a guide to authenticity or quality.

Data Provenance for Researchers

Viewpoints

It's 10 PM; Do You Know Where Your Data Are?

Data Provenance, Curation, and Storage

Mark E. Anderson, Stuart C. Ray

High integrity data retention and curation are critical for preserving the scientific record and informing future discovery.[1] However, these steps are often neglected or inadequate because of lack of a tractable, easily operated approach. We offer general guidelines and an exemplar method that is applicable to many, but by no means all, laboratories.

Data Retention and Provenance

Data generated from National Institutes of Health funding should be stored for 3 years after the end of the last competitive renewal. In some cases, data related to patients and patents has longer storage obligations. Data storage rules are

involving manipulated and repurposed example tracings, published work by us and others, independent of this individual, indicated that his represented findings most likely reflected actual biology. However, the trail of data was incomplete, and most of the publications were over 10 years old. The laboratory notebooks were in hand, but his computer, left behind in a laboratory move, was lost. During the investigation, we repeated many of the key experiments and obtained results similar to those published, but these were unsuitable for replacing the vitiated data because of modern concepts of peer review. These wrenching events led me (M.E. Anderson) and our laboratory to consider improved ways of retaining data, with a focus on a method

Anderson ME and Ray SC. *Circ Res* 2017; 120(10):1551-4

The difference between screwing around and science is writing it down

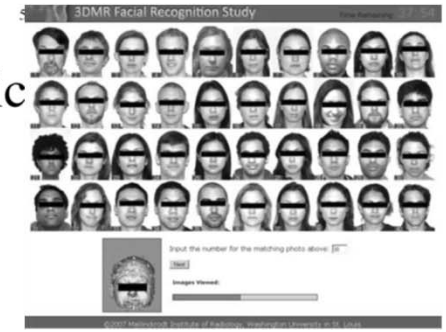
Adam Savage, *Mythbusters*

Facial recognition from 3D reconstruction of surface features from CT and MRI

IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE, VOL. 13, NO. 1, JANUARY 2009

Facial Recognition From Volume-Rendered Magnetic Resonance Imaging Data

Fred W. Prior, *Senior Member, IEEE*, Barry Brunsden, Charles Hildebolt, Tracy S. Nolan, Michael Pringle, S. Neil Vaishnavi, and Linda J. Larson-Prior



J Digit Imaging (2012) 25:347–351
DOI 10.1007/s10278-011-9429-3

Facial Recognition Software Success Rates for the Identification of 3D Surface Reconstructed Facial Images: Implications for Patient Privacy and Security

Jan C. Mazura · Krishna Juluru · Joseph J. Chen · Tara A. Morgan · Majnu John · Eliot L. Siegel

Remedy for facial re-ID risk

- A JHM imaging researcher has tools for segmentation of imaging data, and removal of segments (e.g. the face) that are not needed
- The Data Trust encourages this as a service for researchers who wish to share brain images