

Security governance

Title: Research in the Electronic Age
Technological Tools

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Centre universitaire
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Declaration

Conflict of Interest:

I recognize no financial or business affiliation with any organization that could be perceived as a conflict of interest in the context of this presentation.

Agenda Research@MUHC

- June 2013; changes with Bill#30
- Electronic Technologies in Research
 - Electronic Consent
 - Data Capture (RedCap)
 - Data Storage
 - Other online tools
 - Survey tools
 - SYME
 - WeTransfer

Bill#30: Amend Civil Code & other with respect to research

- In force since June 2013
 - Stated Goal:
 - To modernize Research Legislation (last update 1998)
 - Reconcile Research Interests with patient rights & dignity
- Most important changes (4 of 8):
 - REB is a must for all cases (minors & majors)
 - Talk about Research instead of Experiment
 - Redefine Risks (minimal) and the notion of expected benefits
 - Lots of changes for CONSENT including
 - Minor (14 & over) can give consent if REB says OK
 - **Electronic Consent is now possible**
 - Define who else can give consent

Electronic Technologies in Research

- Evolution is constant
 - Thru innovation & discoveries
- Lack of Guidance on their use
- More reliance on REB to ensure regulation compliance

Electronic Consent (EC)

- Changes say: ““However, consent to such research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent.”

- When is it appropriate?
 - Online Survey Studies
 - Screening
 - In-person paperless survey research
 - Questions answered with the use of an iPad
 - Other situations

- Tri-Council (TCPS2) says:
 - “...consent encompasses a process that begins with the initial contact and carries through to the end of participants’ involvement in the project... legal obligation to bring to participants’ attention any changes to the research project that may affect them.”
 - More than just a signature on a form!

Source: *TCPS2 Ethical Conduct for Research Involving Humans*

Electronic Consent Benefits

■ Participants

- Convenience, less pressure, more informed

■ Researchers

- Higher Enrolment? Higher capability!
- Convenience; no travel
- Paperless

Electronic Consent Challenges

■ Participants:

- Discussion with research staff more difficult
- User interaction must be KISS*
- Confidentiality: Who can access my info?

■ Researchers

- Expensive; Verification & Compliance
 - Are we the first one to do this?
 - Need interactive website with Multimedia
 - Embedded comments in consent forms

*KISS: Keep it simple & stupid

What is Electronic Consent?

■ Two types

- Full “digital signature” using a Legally binding equivalent of handwritten signature!
 - With a magnetic pen (or finger!) on a PAD
 - Using known encryption techno (RSA, Entrust, etc)
- Indication of consent other than a full signature
 - Click on box to consent
 - “by submitted this survey you are consenting to participate in the research”
 - This would require a timestamp!

Data Capture



- REDCap: Research Electronic Data Capture
- Developed by Vanderbilt University (<http://www.project-redcap.org/>)

- User friendly data collection tool
- A solution to improve the quality of your study data

- Overview of REDCap Software Features
 - Login Authentication
 - Web-based: Database from anywhere in the world / no extra software
 - Online: Real time data collection
 - Real time data validation: Data Quality
 - Audit trail: Track the history of your data
 - Export data to common data analysis packages (SAS, R, SPSS)

REDCap@RI-MUHC

- RI-MUHC is currently implementing REDCap in a **Secure, Controlled** and **Validated** environment
- Release is planned for this Spring/Summer 2014
 - More details will be released at a later date as it becomes available
- For more information, please contact us at:
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Electronic Data Storage

- What do to with data after the research is finished?
 - Paper or digital information?
 - DVDs, CDs: Storage is good for X years
 - Maintain data on protected servers
 - How long can you keep data on REDCap?
 - Who will manage this?

Recall of Last Year's Survey tools

- For McGill researchers



- intended for use by McGill faculty and staff for research or administrative purposes*



- For others

- Located in Canada (*vs USA for Monkey Survey*)

These tools can help you gather subject responses that you can then transfer to other analysis tools

Other Internet tools for research



- SYME
- Secured SOCIAL Network on CHROME
- Created by 3 young entrepreneurs; one of them a resident here @MUHC.
- Already used by Security Governance & MUHC's PASP (Public Affairs & Strategic Planning)
- Cryptology validated by peers
- getsyme.com

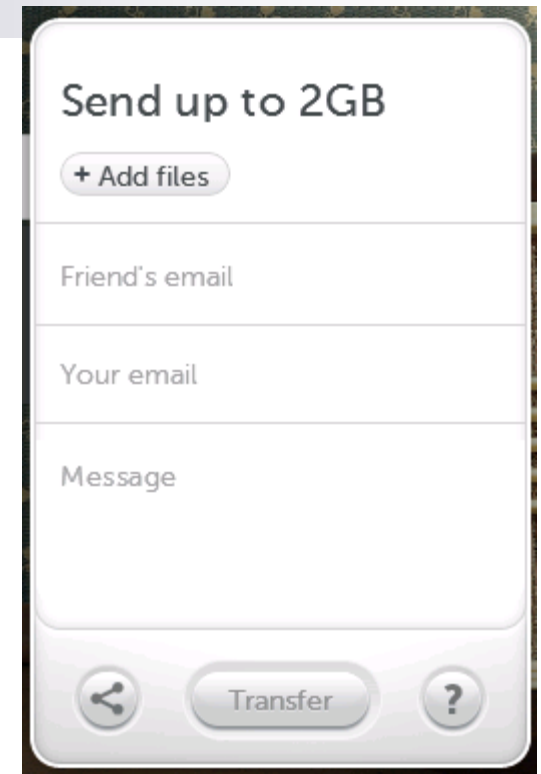
SYME



- You can securely share files (images, documents, videos)
- And secure Chats

WeTransfer

- Based in Netherlands
- Data protection according to: Directive 95/46/EC (till 2015)
- Uses encryption
- Still, we recommend Scrambling file before transfer
- 2Gigs if Free, 10Gigs with Plus (10\$/Year)



QUESTIONS???

Citizen Science

Volunteer collection of biodiversity & environmental data

■ Astronomical

- Galaxy Zoo, milkeyway@home (1997)

■ Environmental; biological

- Colombia river keeper, opal explore nature, Big Butterfly Count

■ Health related

- uBiome project (sequencing technology for microbiome)
- Sage Bionetworks: gather, share, use data in novel ways
- “That’s my data”, “Reg4All”: facilitating flow of patient’s detailed genetic data to researchers in exchange for open access to results.



DataBase Tool

- RexDB, RexQL; Open source research exchange platform

Clinical Trial Management System

- CTMS: Software System & Technology used by health professionals to *manage processes & large amounts of data* involved in Clinical trial management & clinical study management
- eClinical: automating the management or conduct of clinical trials

CTMS; an overview

- Document tracking; forms/templates/instructions
- Subject recruitment/scheduling & visit tracking; planned/unplanned/reporting
- Payment processing; Accrue/internal cost, budget controls
- Clinical supply & inventory management
- Financial tracking & Executive-level reporting

Examples of CTMS environments

- Ascend from



MERGE

CTMS

OnPoint CTMS

(Sharepoint)

