

Law + Tech, In 2 Words
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Research Apps and Consent to Health Research: One Click Away?

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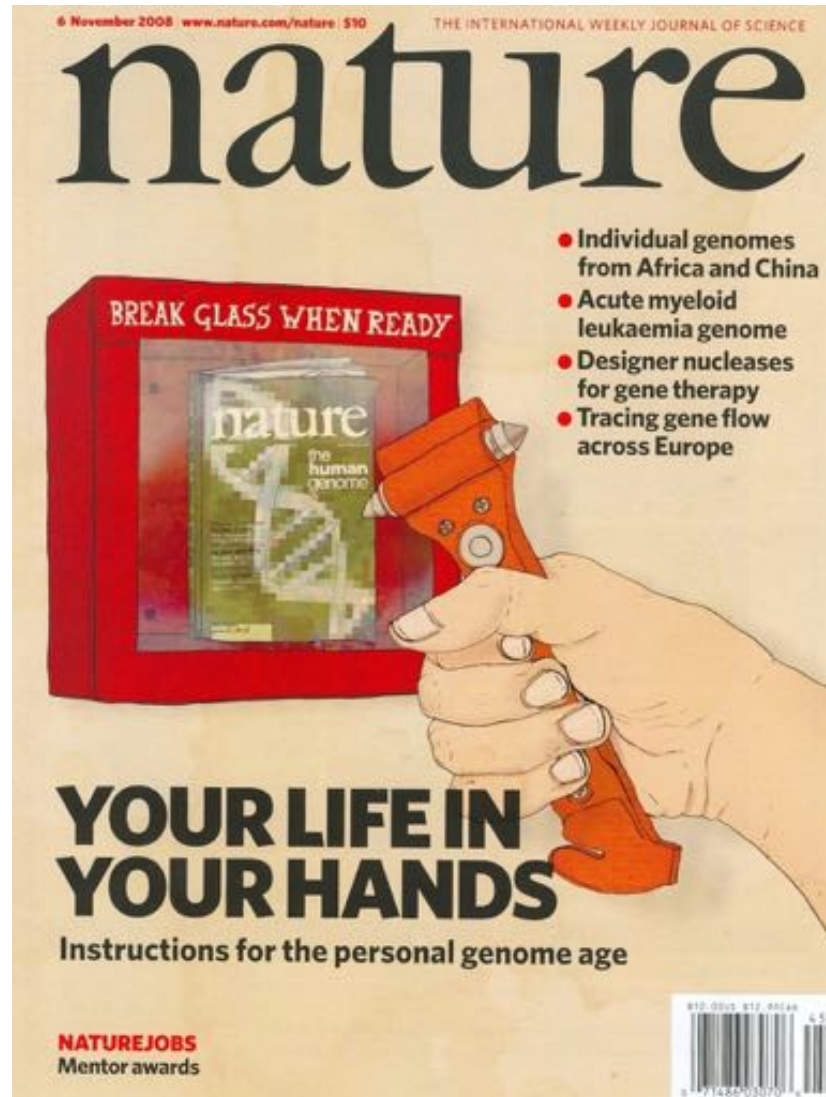
Centre of Genomics and Policy
Centre de génomique et politiques



Content

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- **Furioso: Return of Findings & Practical Issues**

Prelude



Prelude

BY CATHERINE HARRIS

BIODATA



http://whsc.emory.edu/_pubs/momentum/2006fall/biobank.html

Prelude



Intermezzo: Squeezing Out the Doctor?



The Economist, June 2, 2012

Intermezzo: Squeezing Out the Doctor?



Intermezzo: Squeezing Out the Doctor?

- «Approximatively 165,000 health-related apps (m-health);
 - PwC projects that by 2017, m-health apps will have been downloaded over 1.7 billion times;
 - Global revenues will reach \$21.5 billion in 2018 [...], with Europe the largest m-health market”.
- « Things are looking app », The Economist, March 12, 2016

Intermezzo: Squeezing Out the Doctor?



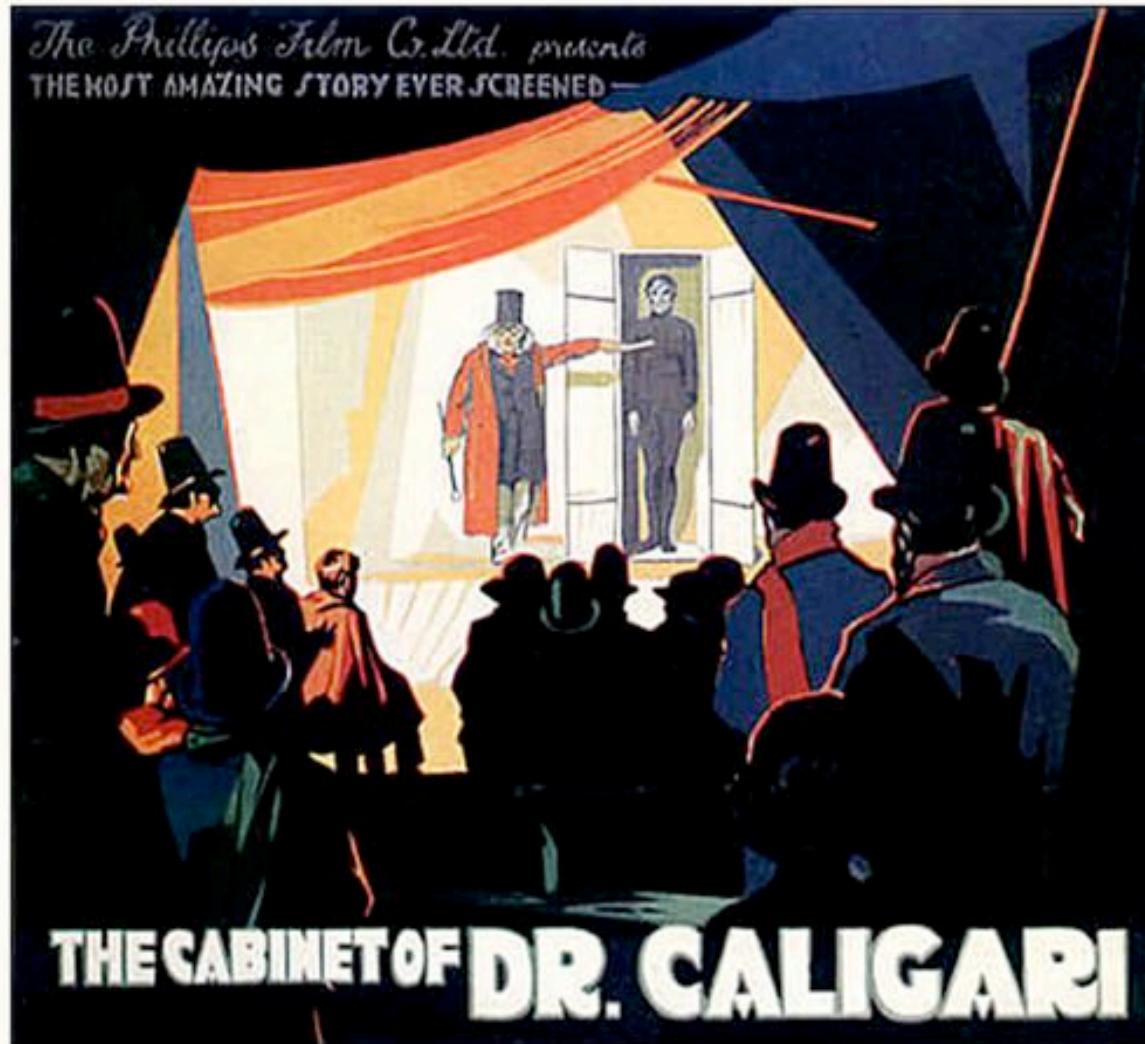
Available at: <http://researchkit.org/>



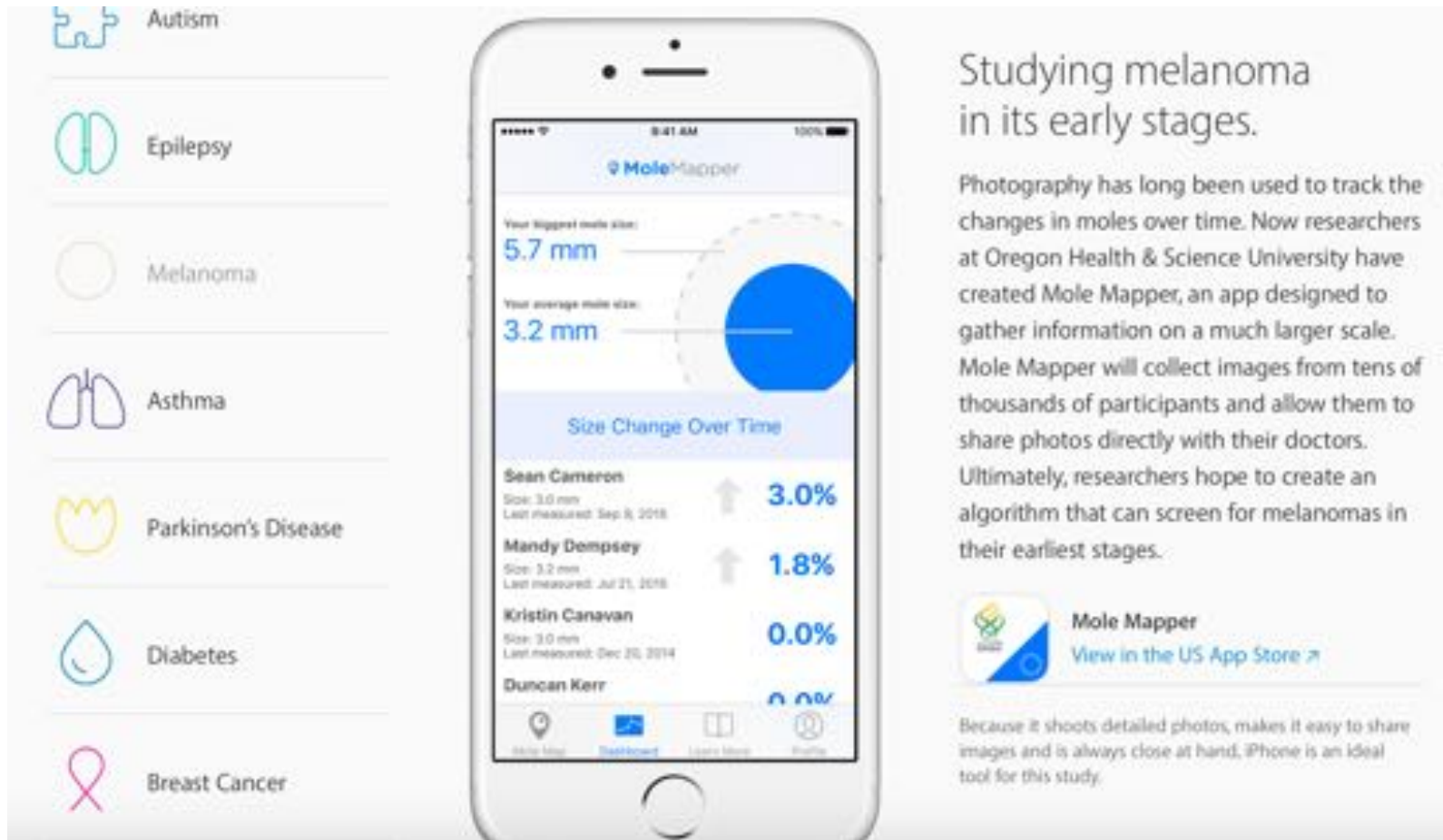
Intermezzo: Squeezing Out the Doctor?

- Research Apps That Strictly Use Data Collected By Itself;
- Research Apps That Integrate Data From External Sources;

Intermezzo: Squeezing Out the Doctor?




Intermezzo: Squeezing Out the Doctor?



The screenshot shows the Mole Mapper app interface. On the left, there is a vertical list of health conditions with corresponding icons: Autism (brain), Epilepsy (eyes), Melanoma (circle), Asthma (lungs), Parkinson's Disease (hand), Diabetes (water drop), and Breast Cancer (ribbon). The central part of the screen displays the app's main interface, which includes the title 'MoleMapper', the time '9:41 AM', and the battery level '100%'. Below the title, it shows 'Your biggest mole size: 5.7 mm' and 'Your average mole size: 3.2 mm'. A large blue circle represents the average mole size, with a dashed line indicating its growth. Below this, a section titled 'Size Change Over Time' lists four users with their mole size changes: Sean Cameron (3.0%), Mandy Dempsey (1.8%), Kristin Canavan (0.0%), and Duncan Kerr (0.0%). At the bottom, there is a navigation bar with icons for Home Map, Dashboard, Learn More, and Profile.

Studying melanoma in its early stages.

Photography has long been used to track the changes in moles over time. Now researchers at Oregon Health & Science University have created Mole Mapper, an app designed to gather information on a much larger scale. Mole Mapper will collect images from tens of thousands of participants and allow them to share photos directly with their doctors. Ultimately, researchers hope to create an algorithm that can screen for melanomas in their earliest stages.

 **Mole Mapper**
[View in the US App Store >](#)

Because it shoots detailed photos, makes it easy to share images and is always close at hand, iPhone is an ideal tool for this study.

Available at: <http://www.apple.com/ca/researchkit/>

Furioso: Return of Findings & Practical Issues





Furioso: Return of Findings & Practical Issues

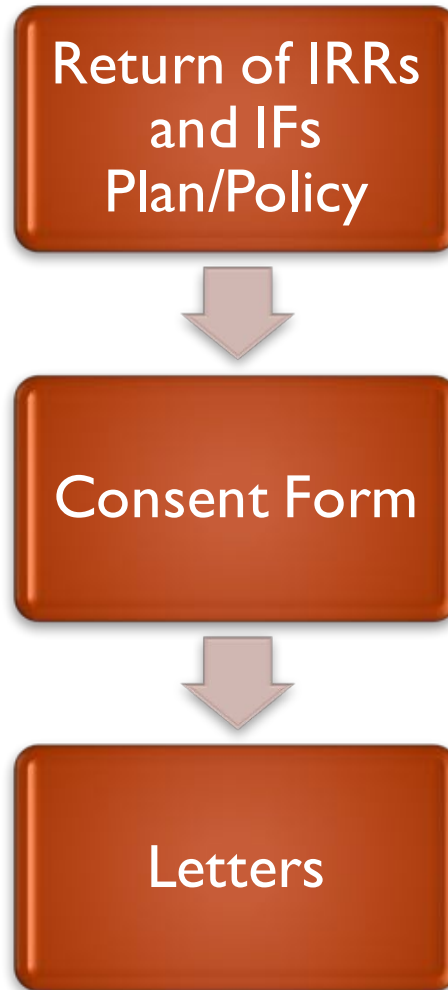
- No specific legislation or case law in Canada on this particular topic;
- Survey of policies and guidelines (international, regional and national) since 2013 on WGS in research (total: 10) = only 40% draw limitations associated with the research/clinical care divide.



Furioso: Return of Findings & Practical Issues

- Article 3.4 *TCPS 2-2014*
- “Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research”
- “A researcher may request an exception to the obligation to disclose material incidental findings, based on the impracticability or impossibility...”
- “Impracticable refers to undue hardship or onerousness that jeopardizes the conduct of the research”.
- Examples included: “when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track”.

Furioso: Return of Findings & Practical Issues





Furioso: Return of Findings & Practical Issues

- Return of Research Results/Incidental Findings Plan must be drafted prior to REB submission;
- Must also be included in the Research Protocol;
- A plan does not necessarily mean return of findings;
- An internal IRRs/IFs Policy (technical aspects included) should be drafted to ensure consistency, especially if the project includes multiple centers;
- If feedback is foreseen, the plan as well as the policy should mention the committee that will make that determination (not an REB);

Furioso: Return of Findings & Practical Issues

Consent Form:

- Researchers must clearly indicate whether they will be returning IRRs and IFs or not;
- If there is a plan to return, participants should be provided with the option of not receiving findings (exceptions for pediatrics);
- If findings are returned, the feedback process should be explained (preferable that a physician of the participant's choice takes on the responsibility of feeding back the info);
- The type of findings to be returned should be delineated, so as not to become an onerous undertaking.
- Researchers must clearly lay out their limitations (experimental methods, requires a clinical evaluation, etc.);

Furioso: Return of Findings & Practical Issues

Communications

- Short and in lay terms for the participants;
- Short and technical for the physician involved;
- Abstain from providing clinical recommendations;
- Reiterate the limitations associated with the findings;
- Communications should respect the choices of participants (i.e. no letter should be sent to individuals if nothing is found).

Thank you !!!



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*Économie, Science
et Innovation*

Québec

