



# MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of  
BRIGHAM AND WOMEN'S HOSPITAL  
and HARVARD

## Towards Streamlined Consent Processes and Participant Understanding

**Barbara E. Bierer, MD**

Faculty Co-Director, MRCT Center

Professor of Medicine, Brigham & Women's Hospital and Harvard Medical School

CBI Conference: Clinical Trial Data Disclosure and Transparency  
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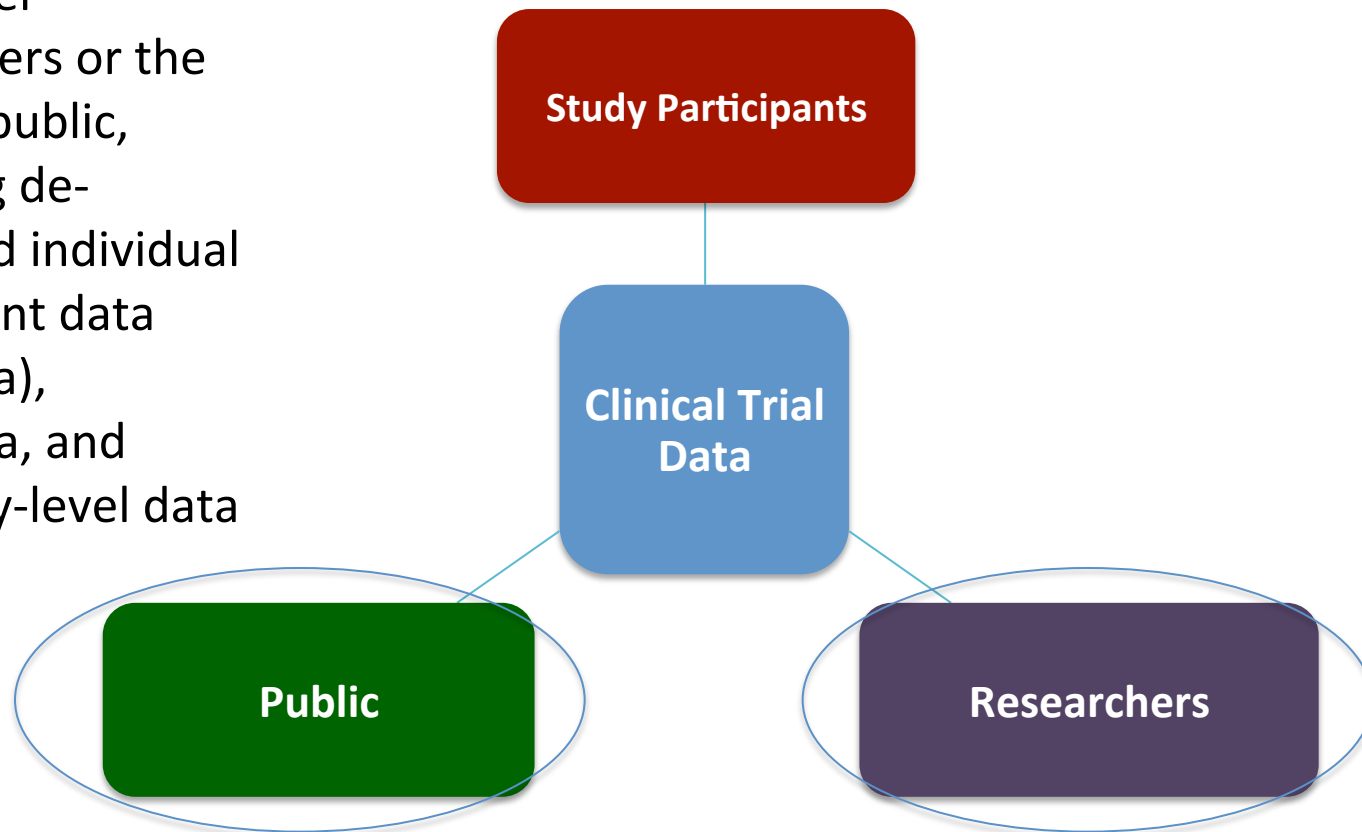
# Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.



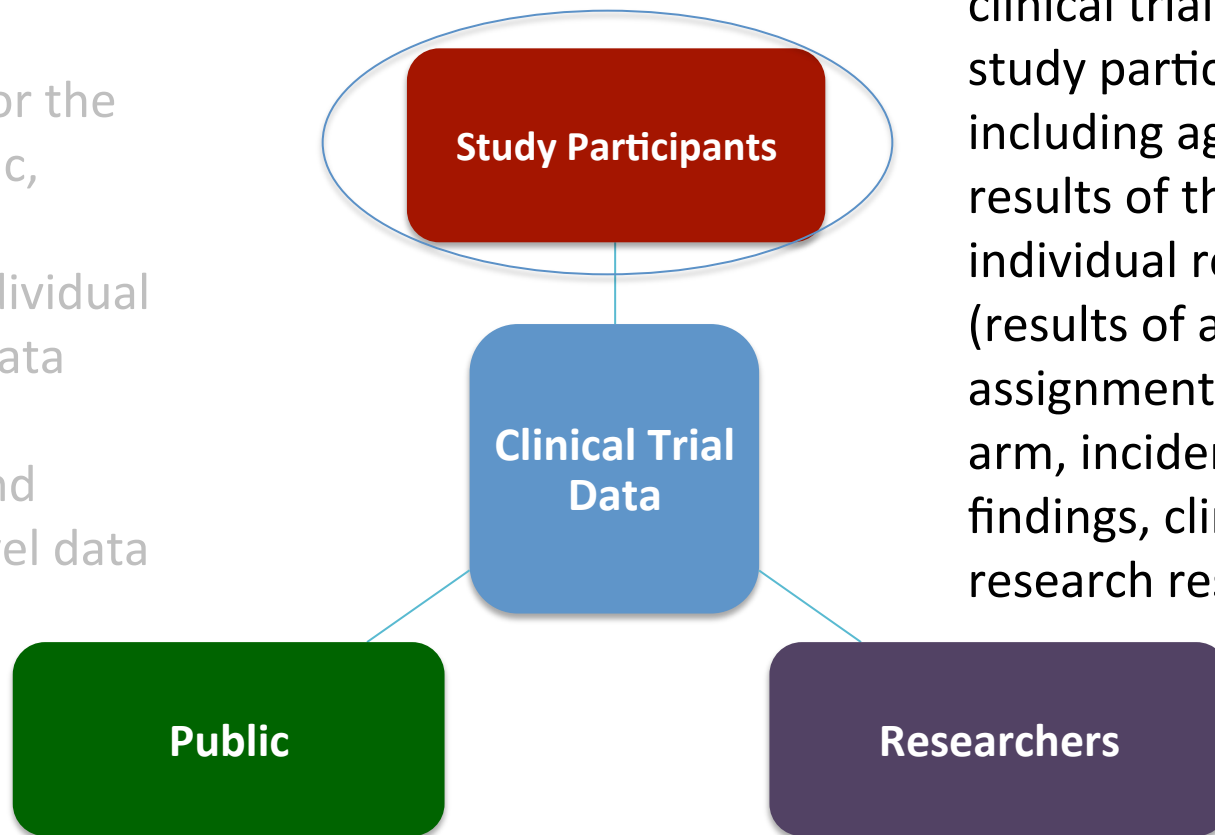
# What is Clinical Trials Data Sharing?

The sharing of data from clinical trials with other researchers or the general public, including de-identified individual participant data (raw data), metadata, and summary-level data



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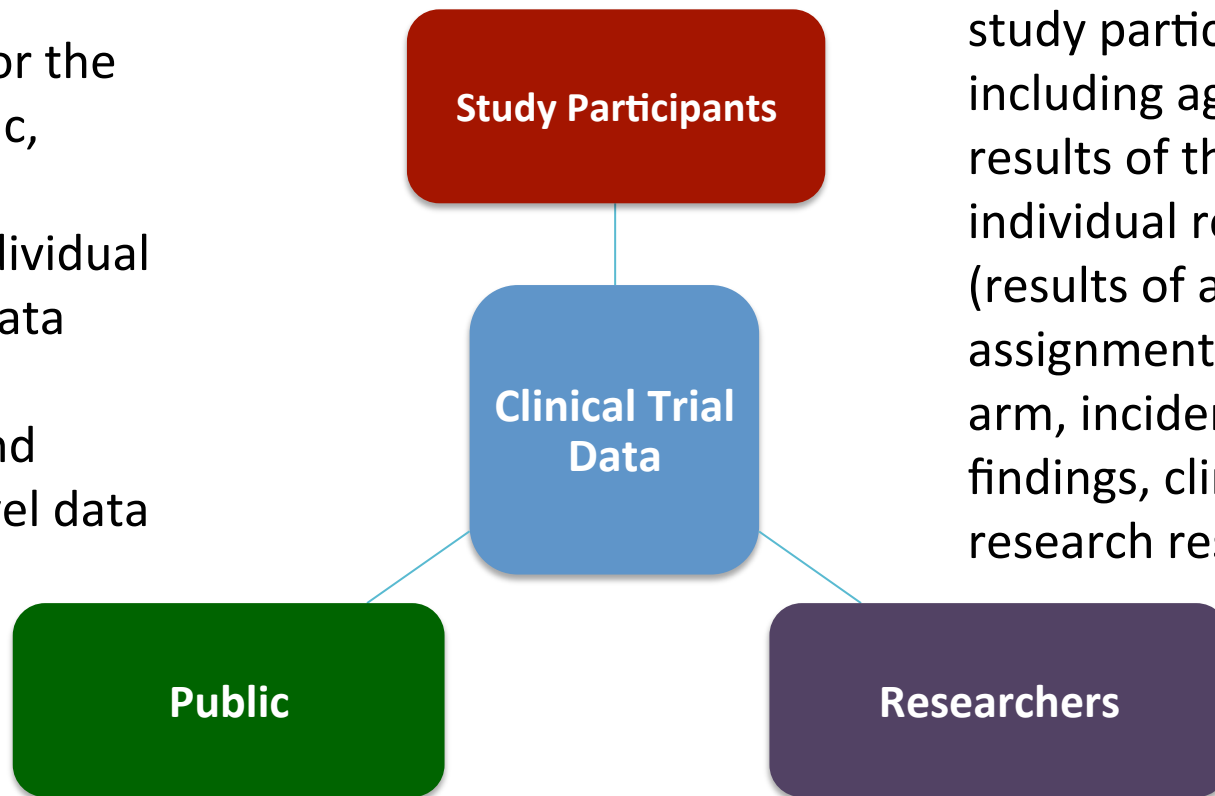
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In both settings, data sharing has important implications for the informed consent process and document for participants.



# Informed Consent conundrum

## ***Informed* consent is hard to achieve**

- Significant problem not restricted to vulnerable populations
- No standard process by which elements of the informed consent are presented and described
- Documentation of comprehension is not required and rarely obtained
- Few well validated methods for comprehension, even fewer for long-term retention of comprehension
  - Teach back



# Required information: consent elements

1. Purpose of the research and procedures;
2. Description of any reasonably foreseeable risks;
3. Benefits associated with participation;
4. Alternatives to participation;
5. Confidentiality assurances;
6. For research involving more than minimal risk, an explanation as to whether any compensation and medical treatments are available if injury occurs;
7. An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time (Department of Health and Human Services [DHHS], 2009).

**NPRM:** A statement about whether or not the subject's data will be used for future research studies if the identifiers are removed



# Additional consent elements

## ***NPRM:***

**Three additional elements** have been added to the other additional elements:

1. Discussion of commercial profit and whether the subject will share in such profit
2. Whether clinically relevant results will be returned to the subject
3. Options for consenting or refusing to consent to be contacted for more information/biospecimens or another research study

Basic elements of informed consent are largely unchanged, with one new element.

Additional elements are generally unchanged with three new added elements (§ \_\_.116(b)(7-9))

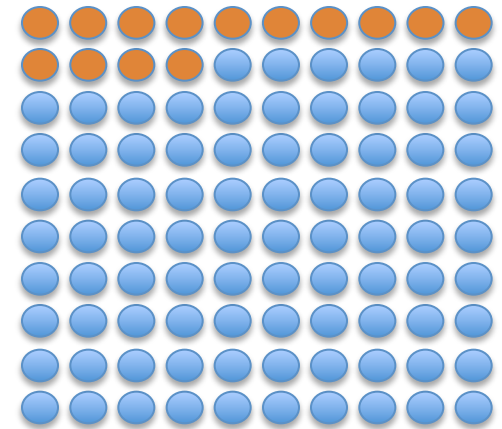
Note that if the NPRM translates to a Final Rule, the FDA has stated that it will amend its regulations to conform to the Final Rule.



# All Communication: Plain language

- Plain language; 6<sup>th</sup> grade reading level or lower
- Use active voice and short sentences
- Formatting to aid comprehension:
- Headlines to organize information
- “Big picture” before the details
- Descriptive headers and subheadings
- Limited use of tables and charts
- Adequate “white space”
- Sufficient contrast between font and background
- Avoidance of text in “all caps”
- Tools such as CDC Clear Communication Index may be used to measure successful application of health literacy principles

14% or ~1 in 7



<http://www.cdc.gov/healthcommunication/ClearCommunicationIndex>



# Data Sharing: Common Informed Consent Language

## TEMPLATE ICF LANGUAGE FOR DATA SHARING

### INFORMED CONSENT LANGUAGE FOR CONFIDENTIALITY AND DATA SHARING

#### **What information about me will be used in the study?**

If you join the study, information about you will be used for the study. This information will be called “your data”. Your data includes personal information that can be used to identify you, such as your name or address. It also includes your birth date and information from your medical record. As part of the study we will get new information about you such as heart rate, blood pressure and results of tests on your blood and other samples. By signing this consent form you agree that ‘Your Data’ can be used as described here.

At any time, you may ask the study doctor to see your personal information and ask to correct it if necessary. In some circumstances, you may not be able to see your study information while the study is ongoing. This is to ensure the reliability of the study. However, the study doctor will share any important medical information if it is relevant to your health during the course of the study.

#### **Who will have access to my information?**

The researchers at the study site (the “Site Study Team”) will give Your Data a unique study code number (such as, 123321). This number will be used in place of your name and other information that directly or easily identifies you (for instance, your address or national identification number.) We will call this new data “Your Coded Data”. The Site Study Team will keep the link between “Your Data” and “Your Coded Data”. They will not send the link to SPONSOR. Your Data that identifies you will remain at the study site. It may be checked by the sponsor, the ethic committee or government agencies that approve medicines to check how the study was run. The Site Study Team will send only Your Coded Data to the sponsor.

#### **How will my information be used?**

SPONSOR will take steps to ensure that your coded data stays confidential and secure. SPONSOR will protect Your Coded Data in accordance with current law. SPONSOR and those working with SPONSOR will use Your Coded Data for research only. They may:

### Issues to address in ICF:

- How data is protected
- How and with whom data may be shared
- Personal information versus personal health information
  - “My data”
  - “Coded data”
  - “Anonymized data”
- Where and with whom data will be shared
- Clinical data (to which participants have a right) versus research data

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- **What information about me will be used in the study?**
- **Who may see and use information about you and your health?**
- **How will my Coded Information be used and protected?**
- **What other general information about this clinical study is shared?**
- **Do I have to participate in this study?**
- **For how long will my data be used?**
- **Can I change my mind about participating in this study?**

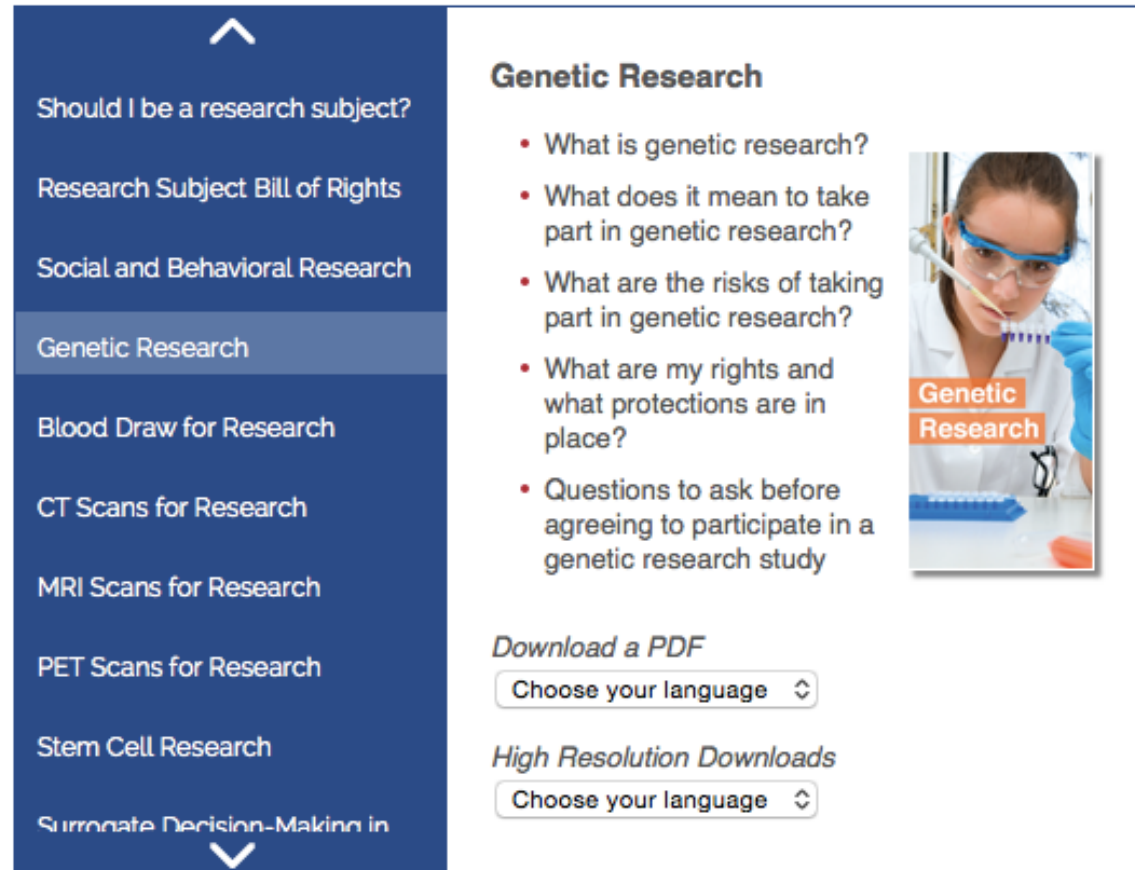
# Alternative approaches

- Invest in preparation

## Brochures

Available in

- English
- Albanian
- Portuguese
- Arabic
- Italian
- Russian
- Cape Verdean
- Khmer/Cambodian
- Spanish
- French
- Korean
- Chinese
- Greek
- Polish
- Vietnamese



The screenshot shows a website interface for genetic research brochures. On the left is a dark blue navigation menu with a white upward-pointing arrow at the top and a downward-pointing arrow at the bottom. The menu items are: 'Should I be a research subject?', 'Research Subject Bill of Rights', 'Social and Behavioral Research', 'Genetic Research' (highlighted in a lighter blue), 'Blood Draw for Research', 'CT Scans for Research', 'MRI Scans for Research', 'PET Scans for Research', 'Stem Cell Research', and 'Surrogate Decision-Making in'. To the right of the menu is the main content area. At the top of this area is the title 'Genetic Research'. Below the title is a list of five bullet points: 'What is genetic research?', 'What does it mean to take part in genetic research?', 'What are the risks of taking part in genetic research?', 'What are my rights and what protections are in place?', and 'Questions to ask before agreeing to participate in a genetic research study'. To the right of the text is a photograph of a female scientist in a white lab coat and blue safety goggles, using a pipette. An orange banner with the text 'Genetic Research' is overlaid on the bottom of the photo. Below the photo are two sections: 'Download a PDF' with a dropdown menu labeled 'Choose your language', and 'High Resolution Downloads' with another dropdown menu labeled 'Choose your language'.

<http://catalyst.harvard.edu/services/rsa/>



# Alternative approaches

- Invest in preparation
- Common presentations and platforms for education and explanations



# Alternative approaches

- Invest in Preparation
- Provide flexibility to explore consent materials

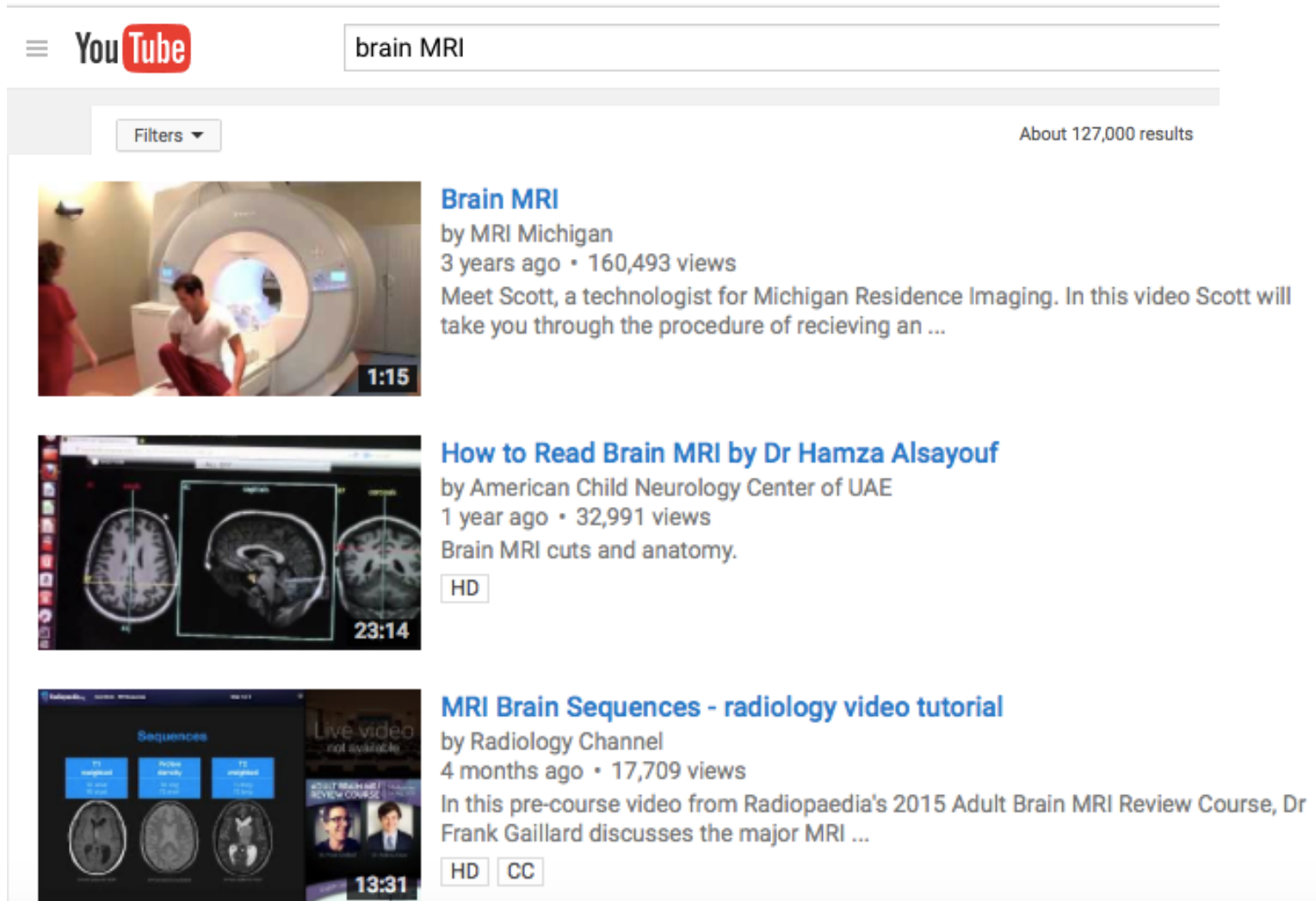
[http://catalyst.harvard.edu/pdf/regulatory/Sophie\\_Science\\_Project.pdf](http://catalyst.harvard.edu/pdf/regulatory/Sophie_Science_Project.pdf)

Developed by Children's Hospital Boston, Cincinnati Children's Hospital Medical Center, and The Children's Hospital of Philadelphia



# Alternative approaches

- Allow use of multimedia tools for IC processes



The image shows a screenshot of a YouTube search results page for the query "brain MRI". The page features three video results. The first video, titled "Brain MRI" by MRI Michigan, shows a person sitting on a table next to an MRI scanner. The second video, titled "How to Read Brain MRI by Dr Hamza Alsayouf", shows a computer screen displaying various brain MRI slices. The third video, titled "MRI Brain Sequences - radiology video tutorial", shows a presentation slide with the word "Sequences" and three columns of text and images. The YouTube interface includes the logo, search bar, filters, and view counts for each video.

YouTube

brain MRI

Filters ▾

About 127,000 results

**Brain MRI**  
by MRI Michigan  
3 years ago • 160,493 views  
Meet Scott, a technologist for Michigan Residence Imaging. In this video Scott will take you through the procedure of receiving an ...  
1:15

**How to Read Brain MRI by Dr Hamza Alsayouf**  
by American Child Neurology Center of UAE  
1 year ago • 32,991 views  
Brain MRI cuts and anatomy.  
HD

**MRI Brain Sequences - radiology video tutorial**  
by Radiology Channel  
4 months ago • 17,709 views  
In this pre-course video from Radiopaedia's 2015 Adult Brain MRI Review Course, Dr Frank Gaillard discusses the major MRI ...  
HD CC

# Informed Consent for data sharing: a look forward

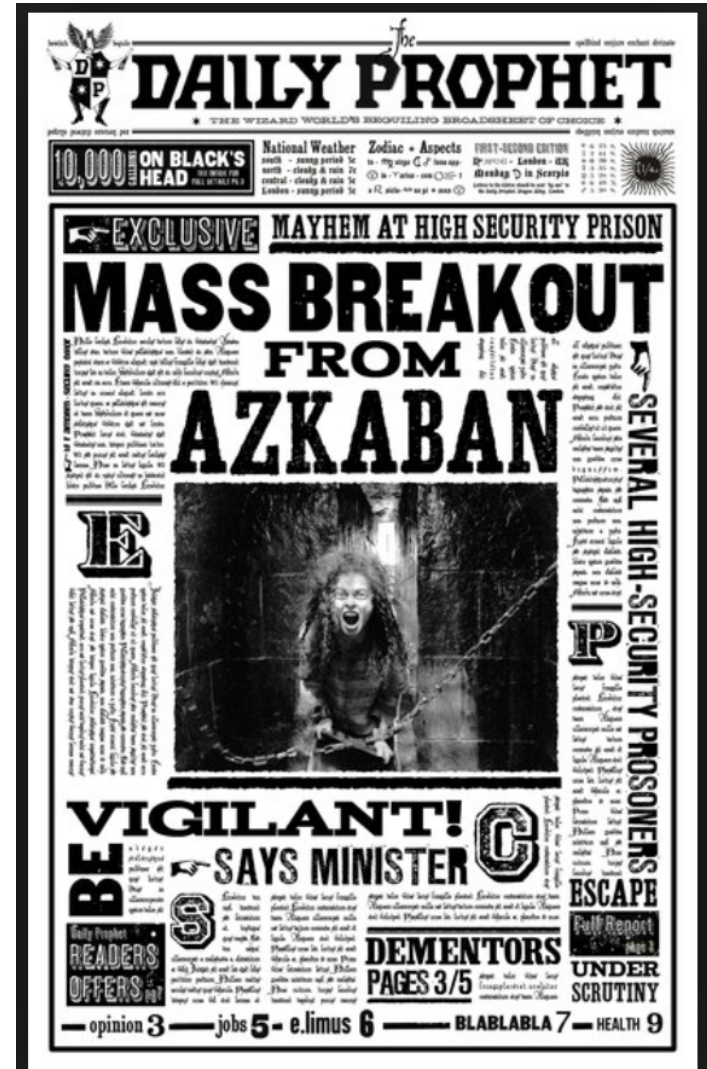
## Invest in Preparation

### Common approach

- Clear definitions, using common terms for common meanings
- Commitment to plain language communication
- Robust, generally available educational platforms, including through social media
- Cultural tailoring of educational materials
- Common informed consent templates
- Interactive, multimedia IC platforms

## Role of eConsents

## Research and data needed



# Questions and Discussion

