NHS
Health Research Authority

Biobank Showcase

Building public confidence in sharing tissue and data for research

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Joint Head of Policy

Joint HRA/HTA public dialogue to understand better what and how we should ask consent for sharing patient data to be linked with donated tissue

The Health Research Authority (HRA)

To protect patients in health research
Approve health research studies

The Human Tissue Authority (HTA)

Provides guidance and sets standards for the removal, storage, and use of human tissue and organs

Sciencewise

Ipsos MORI team
Improvisers
Experts
Independent Evaluator

Ipsos MORI
Social Research Institute

Talking to the public

- General public invited to attend two deliberative workshops
- 3 locations across England
- 25 people in each group
- Members of general public recruited in the street according to a quota
- Experts invited to debate issues with the public

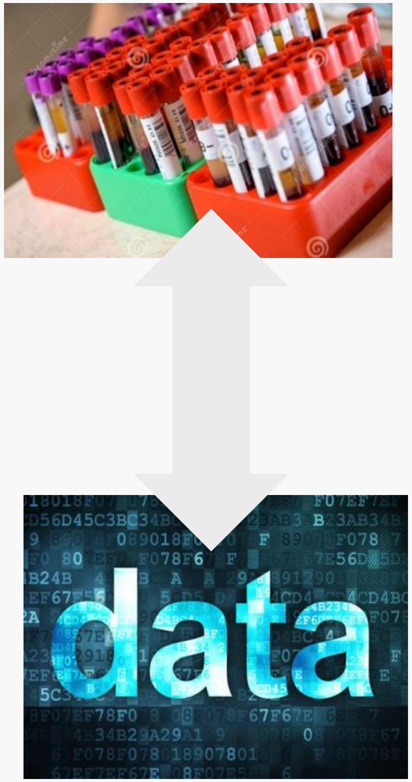
Context

- Tissue of little value without patient data
- Lack of adequate consent at time that tissue sample is taken
- Lack of adequate guidance on consent for sharing future patient data in relation to tissue
- What happens when tissue becomes data?

The big question

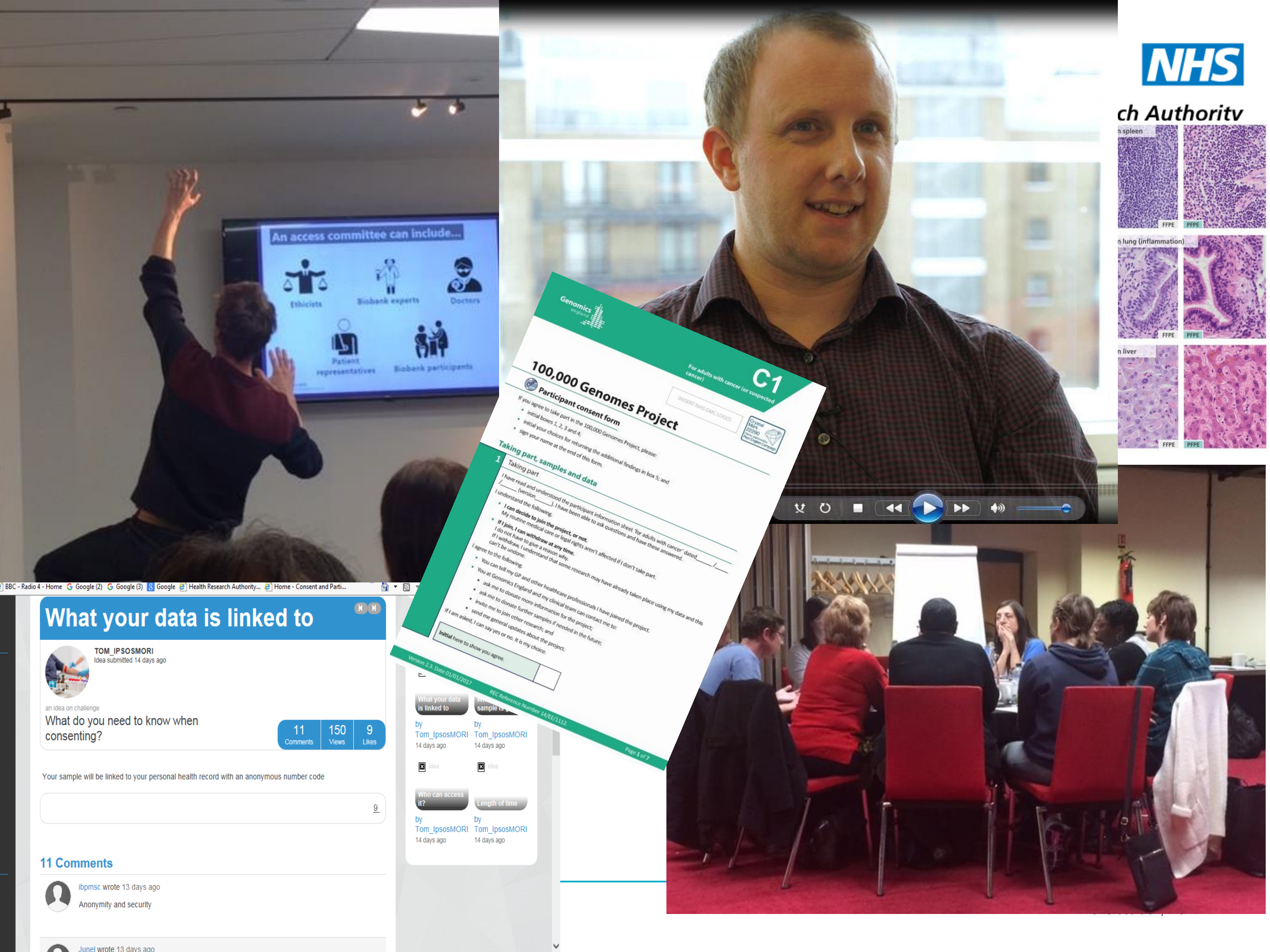
How should researchers seek permission to link patient data with human tissue for health-related research?

- What is the most trustworthy way?
- What are the best ways, to reduce delays and extra costs?
- What exactly do people 'consent' to?



Three areas of discussion

- Biobanks & broad consent
- Genomics England consent
- Dynamic consent



Genomics England

C1

For adults with cancer (or suspected cancer)

[INSERT NHS GMC LOGO]

Crystal Mark 22290 Clarity approved by Plain English Campaign

100,000 Genomes Project

Participant consent form

If you agree to take part in the 100,000 Genomes Project, please:

- initial boxes 1, 2, 3 and 4;
- initial your choices for returning the additional findings in box 5; and
- sign your name at the end of this form.

1 Taking part, samples and data

Taking part

I have read and understood the participant information sheet 'for adults with cancer' dated ____/____/____ (version ____). I have been able to ask questions and have these answered.

I understand the following.

- **I can decide to join the project, or not.** My routine medical care or legal rights aren't affected if I don't take part.
- **If I join, I can withdraw at any time.** I do not have to give a reason why. If I withdraw, I understand that some research may have already taken place using my data and this can't be undone.

I agree to the following.

- You can tell my GP and other healthcare professionals I have joined the project.
- You at Genomics England and my clinical team can contact me to:
  - ask me to donate more information for the project;
  - ask me to donate further samples if needed in the future;
  - invite me to join other research; and
  - send me general updates about the project.

If I am asked, I can say yes or no. It is my choice.

Initial here to show you agree. ☐

Version 2.3. Date 01/01/2017

REC Reference Number 14/EE/1112

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What your data is linked to

TOM_IPSOSMORI
Idea submitted 14 days ago

an idea on challenge

What do you need to know when consenting?

11	150	9
Comments	Views	Likes

Your sample will be linked to your personal health record with an anonymous number code

9

11 Comments

ibpmsc wrote 13 days ago

Anonymity and security

Junel wrote 13 days ago

What your data is linked to
by Tom_IpsosMORI
14 days ago

sample is ...
by Tom_IpsosMORI
14 days ago

☒ idea

☒ idea

Who can access it?
by Tom_IpsosMORI
14 days ago

Length of time
by Tom_IpsosMORI
14 days ago

Some early findings

- Public support the notion of data sharing with tissue donation for research. They clearly understand the public benefit but have some concerns about commercial gain.

- Public are in the main supportive of research, and welcome opportunities for their genetic data to be used.

- Public support consent for unlimited future use of data as well as past

Cont.

- Would like to have ability to opt out of consent for some types of research or researchers
- Room for improvement for current consent forms and need to ensure greater clarity
- Support for notion of dynamic consent but appreciate the costs of setting up
- Strong views on the access committee

An access committee can include…

Ethicists

Biobank experts

Doctors

Patient representatives

Biobank participants

How will we use the results

- Results of public debate will feed into joint HRA/HTA guidance on consent for sharing patient data linked to tissue
- Inform the work of Genomics England
- Building on work already carried out by Wellcome and others on patient data

Thank you

Any questions?

Please send comments suggestions to amanda.hunn@nhs.net