

HEAP schools outreach. Broad consent biobanking activity

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Set up

Activity delivered in classroom format to accompany a field trip to a biobank.

Suitable for age 11 and above

Group size: 15-20 pupils, 2 adult helpers, 1 activity leader

Equipment:

- Two large tables
- Overhead projector (to display powerpoint)
- Two writing boards and pens
- Post its

30-Minute activity: Debate and vote on broad consent for biobanks and safeguard building

Group instructions displayed on powerpoint

Introduction: Present case study on UK Biobank (5 minutes)

Step 1: Divide and Debate (10 minutes)

- Split the class into two groups:
 - Group A: "For Broad Consent" (*see prompts*)
 - Group B: "Against Broad Consent" (*see prompts*)
- Each group prepare 2–3 key points to support their side using their prep notes.
- Each group presents their arguments.
- The other group responds with questions/challenges

Step 2: Safeguard Suggestions (10 minutes) (*see prompts*)

- As a whole class, lead a brainstorm:
"If we were designing our own biobank, what rules would we put in place to make sure people feel safe giving broad consent?"

Write down ideas on the board or a poster.

Prompt with examples like:

- Only approved researchers can access the data.
- Participants can withdraw at any time.

Final vote (5 mins)

How comfortable would you feel donating your samples to a biobank using a broad consent agreement?

(10 - very comfortable, 0 – very opposed)

Instructions:

- Write score on a Post-it, with reasons/comments if you like
- Stick on board

Handout

Broad consent in action - The UK Biobank Case Study

Between 2006 and 2010, the UK Biobank recruited 500,000 volunteers aged 40–69 from across the UK.

Participants gave blood, urine, and saliva samples, completed health and lifestyle questionnaires, and agreed to have their health followed over time through medical records.

Participants gave **broad consent**—agreeing that their data and samples could be used by approved researchers for a wide range of health-related studies, not just the one they initially joined.

This approach enables researchers worldwide to explore many pressing health issues, from cancer and dementia to heart disease and COVID-19, using the same dataset. The flexibility of broad consent helps maximize the value of participant contributions without needing to repeatedly ask for permission for each new study.

However, broad consent raises ethical questions. Some worry that participants may not fully understand how their data could be used in the future or may not support all types of research. To address this, UK Biobank has strong oversight systems, transparency practices, and limits on who can access the data.

In summary, broad consent, as used by UK Biobank, supports large-scale, long-term research by allowing participants to contribute once while enabling many future discoveries—provided ethical safeguards are in place.

Activity leaders' prompts: Against broad consent –Summary of arguments

Here are three reasons why people might choose not to provide **broad consent** to donate samples to a biobank:

1. **Lack of Control Over Future Use:**

Some people may feel uncomfortable giving permission for unknown future research. They might worry that their samples could be used in studies they personally disagree with—such as research involving genetic modification, animal testing, or partnerships with commercial companies.

2. **Privacy and Data Security Concerns:**

Donating biological samples usually involves sharing personal health information. People may worry their data could be misused, leaked, or hacked, even if the biobank promises anonymity and follows strict data protection protocols.

3. **Mistrust of Institutions or Researchers:**

Past unethical research practices, or negative news stories, may cause some people to distrust medical research institutions. This means they might not want to give broad, open-ended consent without knowing exactly how their contributions will be used.

Activity leaders' prompts: In favour of broad consent –Summary of arguments

Here are three common reasons why people might choose to provide **broad consent** to donate samples to a biobank:

1. **Desire to Contribute to Medical Research:**

Many people are motivated by the opportunity to help advance science and improve public health. By giving broad consent, they enable researchers to study a wide range of diseases—potentially leading to new treatments or preventive strategies that benefit future generations.

2. **Trust in the Biobank and Oversight Systems:**

When a biobank is run by a reputable organization with clear ethical guidelines, strong data protections, and transparent oversight, people may feel confident that their samples will be used responsibly. This trust can encourage them to give broad consent for future, unspecified research.

3. **Convenience and Reduced Burden:**

Broad consent allows participants to make a one-time decision, rather than being re-contacted for every new study. This can be seen as more convenient and respectful of their time, while still allowing their samples to contribute to multiple important research projects.

Activity leaders' prompts: Safeguard suggestions for a "new" biobank

"If we were setting up a biobank, what could we do to make sure people feel happy about giving broad consent?"

1. Clear, Transparent, and Accessible Information

- **Informed Consent Process:** Provide a detailed but understandable explanation of the biobank's goals, the type of samples to be collected, how the samples will be used, and the potential risks involved. This should be written in plain language.
- **Dynamic Consent Mechanism:** Allow participants to adjust their consent preferences over time (e.g., opting out of certain types of research).
- **Use of Plain Language:** Avoid jargon or overly technical terms that could confuse participants. Make sure all documentation and consent forms are accessible to people from various educational backgrounds.

2. Confidentiality and Anonymity

- **De-Identification and Coding:** Ensure that samples are anonymized or pseudonymized (identifiers replaced with codes) to protect participants' identities. Any data that could link biological samples back to an individual should be securely stored and accessible only to authorized personnel.
- **Data Encryption and Security:** Establish robust cybersecurity measures to prevent unauthorized access to both biological and personal data.
- **Sharing Guidelines:** Define and clarify who will have access to the data (e.g., researchers, institutions) and under what conditions.

3. Respect for Autonomy and Voluntary Participation



- **Right to Withdraw:** State that participants can withdraw their consent at any time without any negative consequences, and ensure they know how to exercise this right.
- **No Coercion or Pressure:** Ensure that participation is voluntary and that individuals are not coerced into contributing because of financial, medical, or personal pressure.

4. Ethical Oversight and Governance

- **Ethics Committee or IRB Oversight:** Ensure the biobank is subject to ongoing review by an institutional ethics committee or institutional review board (IRB) to guarantee ethical practices and compliance with regulations.
- **Public Accountability:** Maintain an ethical governance structure that involves public stakeholders or an advisory group to review research purposes and ensure transparency.

5. Flexible, Broad Consent with Ongoing Communication

- **Future Research Projects:** Emphasize that research uses can evolve over time, but establish clear procedures for informing participants about the types of future research that their samples might be used for (without detailing every possible study).
- **Regular Updates and Communication:** Keep participants informed of major studies or findings arising from their contributions. Provide them with updates on how their samples have been used and what kinds of research are being conducted.

6. Respect for Participant Preferences

- **Granular Consent Options:** While it is broad consent, consider providing options to opt in or out of specific types of research (e.g., genetic studies, commercial research, or studies involving specific conditions).

- **Cultural Sensitivity:** Take into account cultural or religious sensitivities in the informed consent process, ensuring that all participants feel respected and understood.

7. Data Ownership and Commercialization Concerns

- **Clarifying Ownership and Benefits:** Ensure participants understand the ownership of the samples (e.g., whether they retain any rights) and provide clarity about how any resulting commercial products or profits will be handled.
- **Non-Discriminatory Research Use:** Establish that samples will not be used for discriminatory purposes (e.g., for racial profiling or stigmatization).

8. Ethical and Legal Compliance

- **Compliance with Regulations:** Ensure the biobank is in compliance with local and international regulations (e.g., GDPR in Europe, HIPAA in the U.S.) and ethical standards such as the Declaration of Helsinki.
- **Adherence to National/International Ethical Guidelines:** Follow international ethical principles for research involving human subjects, such as the Belmont Report, which emphasizes respect for persons, beneficence, and justice.

9. Community Engagement and Trust Building

- **Community Consultation:** Engage the community or relevant patient groups in discussions about how the biobank will operate and the kinds of research that will be prioritized.
- **Transparency in Use of Samples:** Set up transparent mechanisms for reporting how samples are being used and the results of research, making it clear to participants that their contribution is valued.

10. Minimizing Risk of Harm

- **Psychological Support for Participants:** Acknowledge that participating in biobanks, particularly in genetic studies, can lead to concerns about the results (e.g., discovering predisposition to a disease). Offer counseling or referrals for psychological support.
- **Minimizing Stigma or Discrimination:** Assure participants that their genetic information will not be used against them in any discriminatory manner (e.g., by employers or insurance companies).

11. Incentives and Compensation

- **Clear Incentive Communication:** If providing incentives, make sure they are explained clearly, so participants don't feel pressured to participate.
- **Equity in Access:** Ensure that all individuals, regardless of socioeconomic background, have equal access to participate.

Results from school visit to IARC – June 2025

Biobank tour:





Broad consent activity: Against:

Against:

- Undefined title for which they have information to BioBanks. Therefore during this time the government can change and can be used for unethical reasons.
- Insurance companies will pay a lot of money to know individual health problems. Therefore, ~~insur~~ they will charge more for fragile individuals, making social and economic inequalities.

Reasons for going against
broad consent.

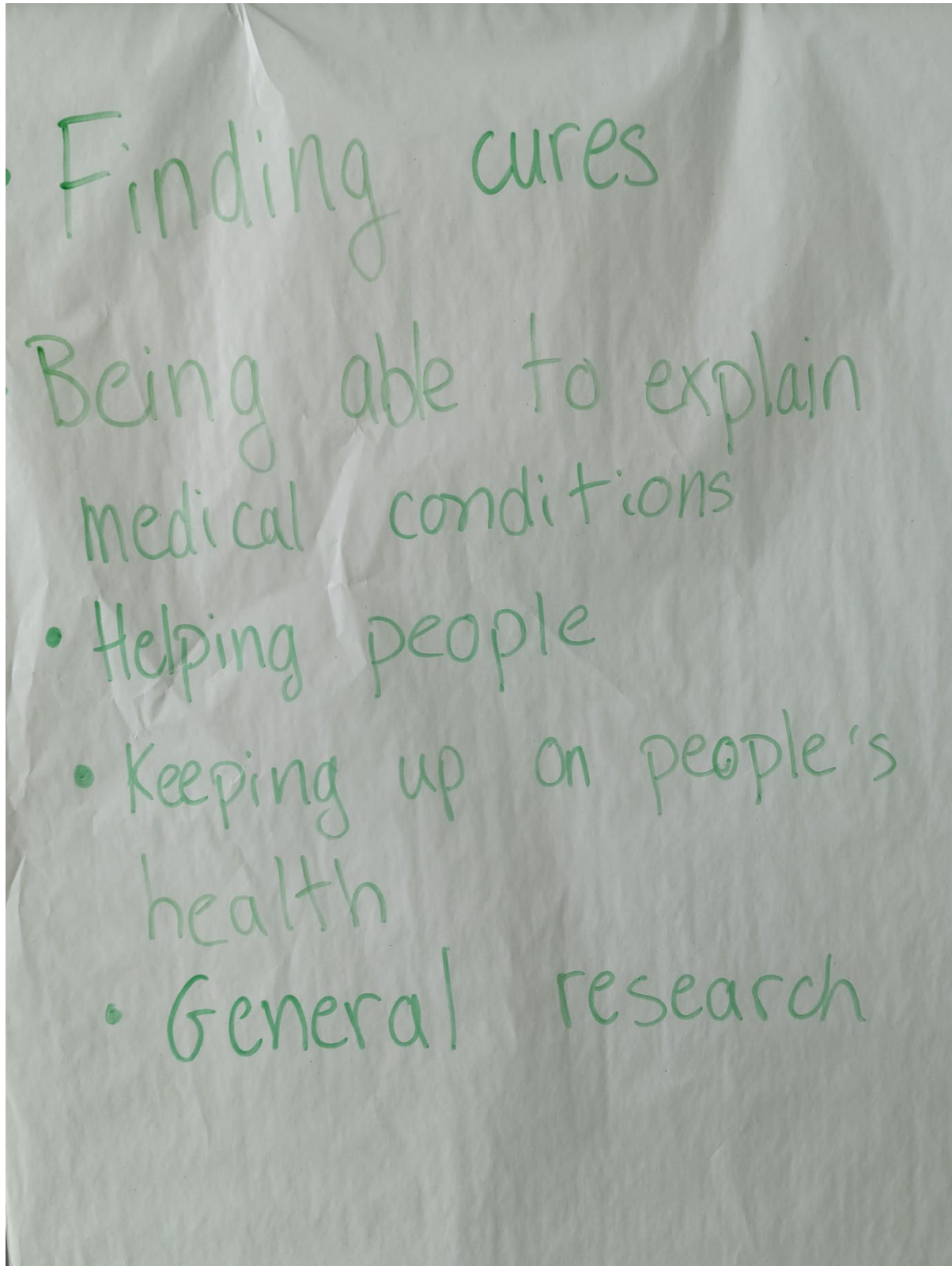
Possible theft of information

Religion/Cultural

Giving data to unknown people

Might not agree to uses of
such information

Broad consent – arguments for



For

- To help future research and people
- Makes the process go faster because you don't need to ask for consent each time
- ~~There~~ There is more data to test and research on

Rules for the new biobank:



A new Biobank

- Explain what research is for
- Financial incentives. 20 EUR?
- Opt out.
- Ethical hacking.

