Guidance on Consent for Future Re-use

Introduction

This document includes template consent clauses and patient information sheet (PIS) guidance intended **solely to cover consent for future research use of samples and data** collected as part of a study. Consent for taking part in the research study itself should be covered in separate clauses. The ambition is to create future-proof broad consent wording that helps to maximise the impact of data and samples collected as part of a study by facilitating the option to re-use. Input from other funding organisations has been sought to help shape and validate this ambition.

The wording and guidance in this document were developed through collaboration with the Health Research Authority (HRA) and a variety of other stakeholders including research nurses, clinical trial operations leaders and more than 50 Patient and Public Involvement and Engagement (PPIE) representatives.

We are aware that each institution may have different capabilities and procedures for obtaining patient consent, therefore we have created two options for the consent wording that are recommended in different scenarios:

1) **Wording Option A**: This option should be used where there is a preference to offer patients the ability to opt-out of different use cases (e.g. commercial use) and your institution has established internal processes that enable efficient and accurate tracking of multiple consent options for each patient.
2) **Wording Option B:** This option should be used where your institution wishes to maintain simplicity in the consent forms and/or may not have the appropriate internal processes in place to enable accurate tracking of multiple consent options for each patient.

If there are other reasons why your institution cannot follow the consent wording in this document, **the clauses on future re-use must meet these minimum key principles:**

- Clearly indicate in the consent clause that data and samples could be shared with organisations in and outside of the UK, and for commercial purposes.
    - This should be complemented by information explaining the approval process for data/sample access requests.
- Do not limit the future research purpose to specific indications or conditions as data can have unexpected broad applications, using ‘health-related’ is strongly advised.
- Clearly state if any genetic analysis may be conducted on the individual’s samples.

For the first year of implementation of this guidance (until March 2027), you are invited to provide your feedback via this form to help inform future amendments to the document.

Consent wording

Option A

Future use of data [and samples]

(Reference to samples to be added if they have been collected)

- ☐ I agree that [samples and] information collected about me in this study can be shared with non-profit organisations in and outside of the UK to support future, ethically approved health-related research. I understand that my personal details that directly identify me, such as name, address and phone number, will not be shared outside of the research team conducting this study.
- ☐ I agree that [samples and] information collected about me in this study can be shared with commercial organisations in and outside of the UK to support future ethically approved health-related research (optional).

(If not already included in the form, consent should be obtained to account for future genetic assessment of samples (as per requirements under Section 45 of the Human Tissue Act, 2004). This is beneficial to include even if this is unknown at the time of the study.)

- ☐ I agree to genetic analysis of my samples as part of [this study and] future ethically approved health-related research (optional)

Option B

Future use of data [and samples]

(Reference to samples to be added if they have been collected)

- ☐ I agree that [samples and] information collected about me in this study can be shared with organisations in and outside of the UK, including commercial organisations, to support future, ethically approved health-related research, including genetic analysis of samples. I understand that my personal details that directly identify me, such as name, address and phone number, will not be shared outside of the research team conducting this study.

Patient information sheet guidance

Researchers should refer to the HRA Consent and Participant Information Guidance when writing Patient Information Sheets (PIS) for a study. In addition, you should refer to the HRA Patient Data and Research Leaflet in the PIS to help patients understand how their data may be used in research.

To complement the consent wording for future research use (detailed in the section above), it is important to include information about future secondary use research in the PIS. The main PIS should provide the primary information about how participant data and samples will be collected, used, stored, and protected. Any additional information about future storage and reuse should explain the governance and access arrangements, while avoiding unnecessary duplication of information already provided.

Based on consultation with PPIE representatives, a few key areas were identified as important to include on future sample/data use (see below). It is still advisable to engage with your own PPIE advisors to tailor the PIS for the specific context of your study.

- **Ethical approval process:** The process for accessing samples and/or data should be explained. It should be made clear that access is always subject to an approval process whereby independent experts review requests to make sure that it is safe, fair and responsible. For example, this may be approval from a Research Ethics Committee, approval under a research tissue or database framework, or review through other appropriate independent governance processes.
- **Profit:** Participants should be informed that they will not receive a share of any profits that might arise from sample and/or data re-use, but it is important to emphasise that their contribution will still drive meaningful improvements in patient care.
- **Commercial uses:** As the word 'commercial' can raise concerns among patients, it is important to help them understand that commercial organisations play a key role in driving medical progress that ultimately benefits future patients. Patients may find it beneficial to see examples of how samples and data may be used in future studies, though it should be made clear that these are not an exhaustive list of applications:
    - *Pharmaceutical companies may use data and/or samples to better understand a disease so that they can identify and develop new treatments that can benefit patients.*
    - *Diagnostic companies may use data and/or samples to develop a test that helps to detect diseases earlier or predict a patient's response to a treatment.*

- **Genetic analysis for re-use**: If not already included, explain what is meant by genetic analysis e.g. this will involve analysing genetic material for the purpose of research. Participants should be informed that genetic analysis could constitute part of a future health-related research study, and that they will not normally be informed of any findings.
- **Withdrawal of consent:** Explain the process of withdrawing consent for reuse, what this means in practice and any limits of withdrawal (e.g. data may be already shared and cannot be removed).
- **Data protection:** This section should be drafted in accordance with the HRA GDPR template. It is important for patients to know where the data will be held, the retention period and emphasise that no personal information will be sent so patients cannot be identified directly. It should also explain whether researchers will receive identifiable information or coded samples and data, and who will hold the information that could link the data or samples back to the participant. PPIE feedback particularly highlighted that it was important to know if samples and data may be sent to researchers outside of the UK and that there will be appropriate data protection standards in place.
- **Data breach:** Explain that there is a process which will be followed by the researchers/institution if a data breach occurs, both for primary purpose and re-use in accordance with the HRA GDPR template. For instance, the organisation may be required by law to notify the Information Commissioner's Office (ICO) of a data breach within 72 hours of becoming aware of it; and if the breach poses a high risk to individuals' privacy, the affected individuals will be informed directly.