Developing Consensus on Access Documentation

The purpose of this breakout discussion was to compare examples of access documentation from a range of biobanks.

Participants were then tasked to chart wording based on how essential it is to have in the documentation, and where it should sit on the generic to specific / essential to expendable spectrum.
**Group 2. Data Linkage**

**What is "data"**
- Clarity for lay audience on anonymisation
- Who accesses data on behalf of the biobank
- What can data be shared with (researchers, commercial)

**Assurance of GDPR compliance**
- Will obey the relevant law, but need that explained to them
- The biobank will not profit from your tissue?

**Policy on workings of data linkage**
- Say what we won't do with your sample/data
- Linkage to specific data sets?

**Essential**
- Generic template
- Suitable in certain circumstances

**Expendable**
- Not suitable for a generic form and not useful to be included
Group 1: Commercial Access

Essential

Suitable for a generic template

- If yes, EQUITABLE commercial access fundamental point.
- Access to researchers (commercial, hospital, academic)
- GOOD research
- for PUBLIC benefit
- Will there be a charge and if so, why?
- Samples are data - appropriate contract when transferring access document and MTA.
- Sample may be for product development.
- Use of positive language e.g. non-commercial gain, exploitation but commercial use or involvement for benefit of public/patient groups.
- Animal research may or may not be involved
- Provide FAQ?
- Protect identity - could the full scope of this be shared as an option though where this is a possibility? As a tiered consent or further information go to website.

Suitable in certain circumstances

- Generic but maybe not needed

Not suitable for a generic form and not useful to be included

Expendable
Group 3: Cost Recovery

Suitable

Patient doesn't get paid
Details of person to send invoice
Applicant will cover costs of processing and storage

Essential

We recover costs for our services
Drafting of an MTA which details cost once application approved

PO or invoice no
Sample processing

Expendable

No cost to patient
Price will vary depending on sample

Not suitable for a generic form. It might be useful to be included in breakdown of costs.
Info on commercial possibility
explain who has access to the data and how
what it means to process anonymised data
explain the roles and terminology (e.g controller/customer)
processing outside of EEA/EU
future-proofing
Genetic but maybe not needed
not suitable for a generic form and not useful to be included
Expendable

Essential
- explain where the data is stored
- what the key usage of the data will be
- feedback on unexpected findings / feedback

Generic
- access to medical records
- cost recovery / commercialisation / won't benefit financially

Specific
- combining datasets
- access to registry (PHE/NHS Digital)
- PIS: No need to return to patients
- Info for animal use as a possibility
- PIS: clear assessment required whether or not results is fed back
- PIS: class as sensitive if required

Group 6: supplying data
8. Description of Research - Access Form

Essential

- Lay summary for participants and ethics applications
- Purpose of research
- Aim and hypothesis
- Methods to ensure samples suitable
- Experience of research group to support hypothesis
- Would research generate incidental findings?
- For specific disease biobanks is research valid use of samples
- Has this research already been carried out? Some biobanks would not release samples to repeat the same measures

Expendable

- Why this biobank? Eg should samples from cancer patients be released for non-cancer research
- Is research within scope of consent
- Which other biobanks have you applied to? So can tell if there is duplication
- Facilities available to allow work - safety and equipment
- Not suitable for a generic form and not useful to be included

Generic but maybe not needed

- Power calculations to make sure sample size is sufficient for research
Group 9: Description of Teams/Skills

- name and role of contact if different to the investigator
- institution and group
- experience relevant to application
- POC details for the Biobank itself
- default internal affiliation/address could be useful if get lots of internal applications
- shipping address and CONTACT

Generic but useful:
- Degree/Qualification: depends on the type of Biobank? - most applicants will be qualified by their title eg Prof, Dr etc.

Not suitable for a generic form and not useful to be included:
- middle initial
- MTA information
- Sample information
**Group 10: Design and Formatting**

**Essential**
- Multilingual
- Table of contents
- E.g. Less than one page

**Suitable for all documents**
- Name of biobank
- Font size 12 (or 72)
- Intendations
- Line heights/spacing
- Font friendly for people with dyslexia

**Suitable in certain circumstances**
- Font size to differentiate titles and descriptions (but maximum 2)
- Alternative versions for certain patients (colour blind, youths)
- Numbering paragraphs for easier finding
- T&Cs in paragraphs rather than a long essay

**Generic**
- Aesthetic
- Using brand colours
- Schematics & infographics
- Put T&Cs in the form of an appendix

**Specific**
- Personal touch on PIS - thank you for participation
- Use of "you" and not a passive form

**Expendable**
- Relating to requirements of regulations and different policies in access application form that could be covered in agreement
- Consent in bullets/tables, visually separated

**Keeping table simple on Consent Form**