Informed Consent Forms for Data Sharing

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Managing and Sharing Research Data: What is new with the GDPR?
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UK Data Service

Disclaimer

- The information provided in this presentation is based on my current interpretation of the legislation and its implications for research and the archiving of research data
- Based upon the GDPR and the Data Protection Bill (at 18.01.2018)
- Very fluid area and thus changes are still possible
- This presentation **does not constitute, or should not be construed as, legal advice and/or guidance**

Overview

- Informed consent is the process by which a researcher discloses appropriate information about the research so that a participant may make a voluntary, informed choice to accept or refuse to cooperate

- Normally informed consent is given before the start of the research

- Gaining informed consent is crucial to meet your legal and ethical obligations towards participants whilst simultaneously enhancing the value of your research data

The grounds for processing ‘Personal Data’

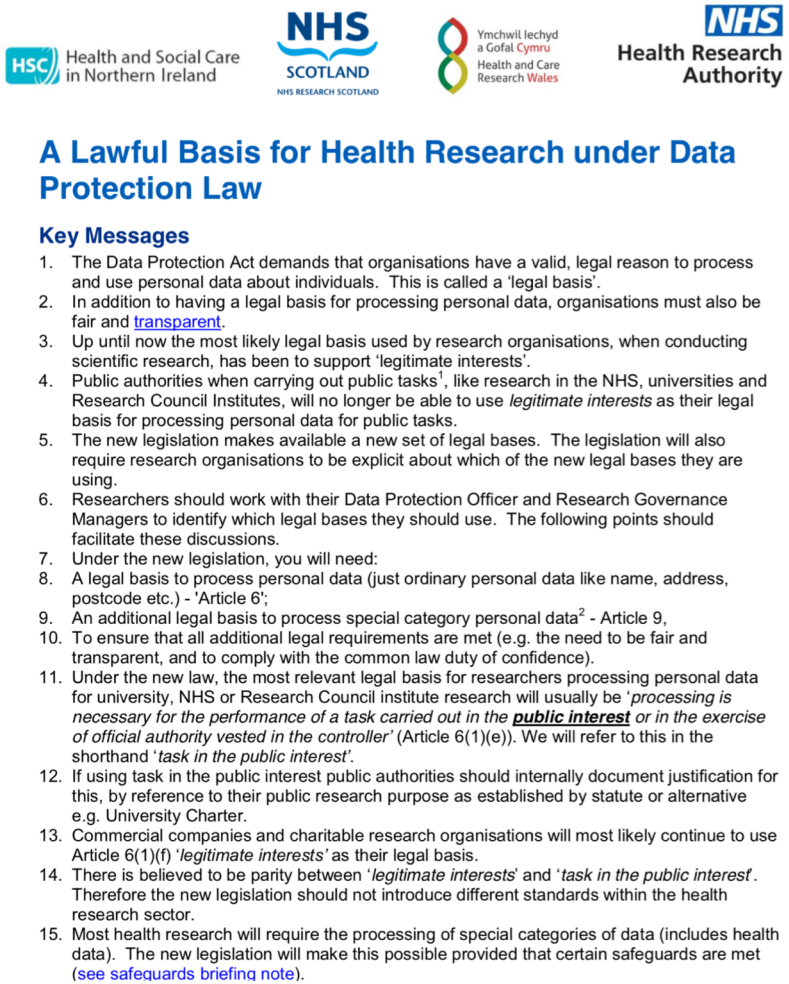
- There are **6** grounds for the processing of personal data, and one of these must be present in order to process a data subject’s personal data:

1. Consent of the data subject
2. Necessary for the performance of a contract
3. Legal obligation placed upon controller
4. Necessary to protect the vital interests of the data subject
5. Carried out in the public interest or is in the exercise of official authority
6. Legitimate interest pursued by controller

Lawful basis for research?

- Currently seems to be three strands of thought (broadly speaking): (i) **consent** or (ii) public interest (**public task**) or (iii) **legitimate interests**
- Note, it ***does not*** have to be **consent**
- Can use other grounds for processing personal data; ***but***, can still gain informed consent for other ethical and legal reasons (just not the processing of personal data)

- https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/



Health and Social Care in Northern Ireland | NHS Scotland | Ymchwil Iechyd a Gofal Cymru Health and Care Research Wales | NHS Health Research Authority

A Lawful Basis for Health Research under Data Protection Law

Key Messages

1. The Data Protection Act demands that organisations have a valid, legal reason to process and use personal data about individuals. This is called a 'legal basis'.
2. In addition to having a legal basis for processing personal data, organisations must also be fair and transparent.
3. Up until now the most likely legal basis used by research organisations, when conducting scientific research, has been to support 'legitimate interests'.
4. Public authorities when carrying out public tasks[1], like research in the NHS, universities and Research Council Institutes, will no longer be able to use *legitimate interests* as their legal basis for processing personal data for public tasks.
5. The new legislation makes available a new set of legal bases. The legislation will also require research organisations to be explicit about which of the new legal bases they are using.
6. Researchers should work with their Data Protection Officer and Research Governance Managers to identify which legal bases they should use. The following points should facilitate these discussions.
7. Under the new legislation, you will need:
8. A legal basis to process personal data (just ordinary personal data like name, address, postcode etc.) - 'Article 6';
9. An additional legal basis to process special category personal data[2] - Article 9,
10. To ensure that all additional legal requirements are met (e.g. the need to be fair and transparent, and to comply with the common law duty of confidence).
11. Under the new law, the most relevant legal basis for researchers processing personal data for university, NHS or Research Council institute research will usually be '*processing is necessary for the performance of a task carried out in the **public interest** or in the exercise of official authority vested in the controller*' (Article 6(1)(e)). We will refer to this in the shorthand '*task in the public interest*'.
12. If using task in the public interest public authorities should internally document justification for this, by reference to their public research purpose as established by statute or alternative e.g. University Charter.
13. Commercial companies and charitable research organisations will most likely continue to use Article 6(1)(f) '*legitimate interests*' as their legal basis.
14. There is believed to be parity between '*legitimate interests*' and '*task in the public interest*'. Therefore the new legislation should not introduce different standards within the health research sector.
15. Most health research will require the processing of special categories of data (includes health data). The new legislation will make this possible provided that certain safeguards are met (see safeguards briefing note).

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Distinguish consent

- When consent is the legal basis for conducting research in accordance with the GDPR, this consent for the use of personal data should be distinguished from other consent requirements that serve as an ethical standard or procedural obligation

- Working Party 29 guidance on consent 10 April 2018

Informed consent (broadly)

- Consent needs to be **freely given**, **informed**, **unambiguous**, **specific** and by a **clear affirmative** action that signifies agreement to the processing of personal data

- When special categories data are processed – *and the processing grounds for this is consent* – there is a further requirement to the above that this must be based on **explicit consent** * *Note Article 9(2)(j) research* *

‘Explicit’ consent

- The term explicit refers to the way consent is expressed by the data subject
- It means that the data subject must give an **express statement** of consent.
- An obvious way to make sure consent is explicit would be to expressly confirm consent in a **written statement**
- In **theory**, the use of **oral statements** can also be sufficiently express to obtain valid explicit consent, however, it **may be difficult to prove** for the controller that all conditions for valid explicit consent were met when the statement was recorded
- **Two stage verification** of consent can also be a way to make sure explicit consent is valid

- Working Party 29 guidance on consent 10 April 2018

Documenting consent

- Under the GDPR, consent needs to be **documented**, which means (in the context of research) it will be important for researchers to maintain documented and accurate records of the consent obtained from their participants

- This could, for example, be written consent or audio recorded oral consent

- Though the GDPR does not require this consent to be in a written form, many UK research ethics committees and professional bodies do require this or recommend it as best practice

Informed consent – research (1)

To obtain informed consent in practice, researchers should:

- Inform participants about the purpose of the research
- Discuss what will happen to their contribution (including the future archiving and sharing of their data)
- Indicate the steps that will be taken to safeguard their anonymity and confidentiality
- Outline their right to withdraw from the research, and how to do this

Informed consent – research (2)

- When seeking to obtain informed consent from participants, it is important for researchers to also consider the specific circumstances and needs of the participants

- This may mean, for example: pictures or diagrams are used on the consent form instead of using a lot of text or the consent form is translated into another language

Informed consent – research (3)

- The GDPR recognises that it is often not possible to **fully identify** the **purpose** of the personal data processing in research at the time of **data collection** and, therefore, data subjects should be able to give their **consent** to **certain areas** of the **research** (in keeping with recognised ethical standards for research)

Recital 33

Informed consent – data sharing (1)

- Gaining informed consent for data sharing is seen as 'one more small step' to gaining consent from participants to partake in a research project
- Adding the discussion of data sharing and archiving permits the participant to make an informed decision
- This empowers them and puts them in charge of choosing whether they wish for their contribution to the research project – and their data – to be available for use in future research projects

Informed consent – data sharing (2)

- The best way to achieve informed consent for data sharing is to **identify** and **explain** the **possible future uses of their data** and offer the participant the option to consent on **a granular level**

- For example, in a qualitative study, this may involve allowing the participant to consent to data sharing of the anonymised transcripts, the non-anonymised audio recordings and the photographs

Informed Consent for [name of study]

Please tick the appropriate boxes	Yes	No

1. Taking part in the study

I have read and understood the study information dated [DD/MM/YYYY], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction. ☐ ☐

I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason. ☐ ☐

I understand that taking part in the study involves [……]. ☐ ☐

> Describe in a few words how information is captured, using the same terms as you used in the information sheet, for example: an audio-recorded interview, a video-recorded focus group, a survey questionnaire completed by the enumerator, an experiment, etc.].
>
> For interviews, focus groups and observations, specify how the information is recorded (audio, video, written notes).
>
> For questionnaires, specify whether participant or enumerator completes the form.
> For audio or video recordings, indicate whether these will be transcribed as text, and whether the recording will be destroyed.

If there is a potential risk of participating in the study, then provide an additional statement:
I understand that taking part in the study has [……] as potential risk. ☐ ☐

2. Use of the information in the study

I understand that information I provide will be used for [……]. ☐ ☐

> List the planned outputs, e.g. reports, publications, website, video channel etc., using the same terms as you used in the study information sheet.
> Consider whether knowledge sharing and benefits sharing needs to be considered, e.g. for indigenous knowledge.

I understand that personal information collected about me that can identify me, such as my name or where I live, will not be shared beyond the study team. ☐ ☐

> At times this should be restricted to the researcher only.

Potential additional statements

i) If you want to use quotes in research outputs: I agree that my information can be quoted in research outputs. ☐ ☐

ii) If you want to use named quotes: I agree that my real name can be used for quotes. ☐ ☐

iii) If written information is provided by the participant (e.g. diary): I agree to joint copyright of the [DD/MM/YYYY] to [name of researcher]. ☐ ☐

3. Future use and reuse of the information by others

I give permission for the [specify the data] that I provide to be deposited in [name of data repository] so it can be used for future research and learning. ☐ ☐

> Specify in which form the data will be deposited, e.g. anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit.
>
> Specify whether deposited data will be anonymised, and how. Make sure to describe this in detail in the information sheet.
>
> Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.

Informed consent form content

- Break down into 3 key areas:

I. Taking part in the study

II. Use of the information in the study

III. Future use and reuse of the information by others

(i) Taking part in the study

1. Taking part in the study

I have read and understood the study information dated [DD/MM/YYYY], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction. ☐ ☐

I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason. ☐ ☐

I understand that taking part in the study involves [……]. ☐ ☐

> Describe in a few words how information is captured, using the same terms as you used in the information sheet, for example: an audio-recorded interview, a video-recorded focus group, a survey questionnaire completed by the enumerator, an experiment, etc.].
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(ii) Use of the information in the study

2. Use of the information in the study

I understand that information I provide will be used for [.....]. ☐ ☐

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iii) If written information is provided by the participant (e.g. diary): I agree to joint copyright of the [DD/MM/YYYY] to [name of researcher]. ☐ ☐

(iii) Future use and reuse of the information by others

3. Future use and reuse of the information by others

I give permission for the **[specify the data]** that I provide to be deposited in **[name of data repository]** ☐ ☐ so it can be used for future research and learning.

Specify in which form the data will be deposited, e.g. anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit.

Specify whether deposited data will be anonymised, and how. Make sure to describe this in detail in the information sheet.

Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.

Timing and form of consent

	Advantage	Disadvantage
Written consent	More solid legal ground, e.g. participant has agreed to disclose confidential info Often required by Ethics Committees Offers more protection for researcher (as they have written documentation of consent)	Not possible for some cases: infirm, illegal activities May scare people from participating (or have them think that they cannot withdraw their consent)
Verbal consent	Best if recorded	Can be difficult to make all issues clear verbally Possibly greater risks for researcher (in regards to adequately proving participant consent)

	Advantage	Disadvantage
One-off consent: participant is asked to consent to taking part in the research project only once.	Simple Least hassle to participants	Research outputs not known in advance Participants will not know all info they will contribute
Process consent : participant's consent is requested continuously throughout the research project	Ensures 'active' consent	May not get all consent needed before losing contact Repetitive, can annoy participants

Information sheet

- 3 key areas:

A. General information about the research and the collected research data

B. Additional information if personal information is collected from participants

C. GDPR considerations

(A) General information about the research and the collected research data

- Purpose of the research
- Type of research intervention, e.g. questionnaire, interview, etc
- Voluntary nature of participation
- Benefits and risks of participating
- Procedures for withdrawal from the study
- Usage of the data during research, dissemination and storage, including how the information will be shared with participants and any access and benefits-sharing that may be applicable (e.g. traditional knowledge under the Nagoya protocol)
- Future publishing, archiving and reuse of the data, explaining to participants the benefits of data sharing and indicating whether research data will be deposited in a data repository, naming the organisation responsible for the repository (e.g. UK Data Service, your institutional repository)
- Contact details of the researcher, with institution, funding source, how to file a complaint

(B) Additional information if personal information is collected from participants

- How personal information will be processed and stored, and for how long (e.g. signed consent forms, names or email addresses in online surveys, people's visuals in video recordings)
- Procedures for maintaining confidentiality of information about the participant and information that the participant shares
- Procedures for ensuring ethical use of the data: procedures for safeguarding personal information, maintaining confidentiality and de-identifying (anonymising) data, especially in relation to data archiving and reuse

(C) GDPR considerations

- The starting point for this should be identifying the **grounds** on which the **personal data** are being processed
- Which ground is chosen will impact on what the information sheet and the informed consent form should include
- **If** consent is chosen as the process grounds then it needs to be **freely given**, **informed**, **unambiguous**, **specific** and by a clear **affirmative action**, and the participant needs to be made aware that they can withdraw their consent at any time, and that will not affect the lawfulness of the processing up to that point

(C) GDPR considerations

- The contact details of the researcher, the data controller (which will likely not be the researcher), and the Data Protection Officer
- Who will receive or have access to the personal data, including information on any safeguards if the personal data is to be transferred outside the EU
- The period of retention for holding the data or the criteria used to determine this
- The right of the participant to request access to their personal data and the correction (rectification) of removal (erasure) of such personal data
- A reminder that the participants have the right to lodge a complaint with the Supervisory Authority (ICO)

Questions

Contact details:

Collections Development and Producer Relations team
UK Data Service
University of Essex
ukdataservice.ac.uk/help/get-in-touch