Health Research Authority

Guidance for researchers and study coordinators on implications of the General Data Protection Regulation for the delivery of research in the UK

The General Data Protection Regulation (GDPR) comes into force on 25 May 2018. In most cases the impact on individual research projects will be limited. This guidance is aimed specifically at researchers, sites and sponsors managing individual research projects.

The HRA has published technical briefing notes relevant at an organisational level for NHS R&D offices, university research offices, company senior managers, Data Protection Officers (DPO), or information governance leads / security architecture leads.

The guidance is published as a living document that will be updated over the coming weeks.

1. Definitions

In this document we use 'GDPR' to refer to requirements in both the EU General Data Protection Regulation and the forthcoming UK Data Protection Act[1].

The term 'Personal data' is defined as in the above regulations. This document only relates to personal data of research participants or potential participants.

> 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Note that personal data that has been pseudonymised – e.g. key-coded – can fall within the scope of the GDPR depending on how difficult it is to attribute the pseudonym to a particular individual.

The term 'confidential patient information' is defined as information to which a duty of confidentiality is owed under common law. Personal data including any health related information (including where health related information can be derived from

[1] The Data Protection Bill is currently going through Parliament https://services.parliament.uk/bills/2017-19/dataprotection.html

context) or health related information in a context from which personal data can be identified, would be confidential patient information.

2. Background

2.1 Consent

Historically, most research studies that have involved use of confidential patient information have sought consent from participants. This meets ethical expectations to promote the autonomy and privacy of research participants. Legally speaking, consent was obtained to avoid a breach of the common law duty of confidentiality. This is not changing with the introduction of the GDPR.

The GDPR requires each activity of processing data to have a legal basis under this legislation, in addition to the common law basis. For health and social care research, the legal basis is determined by the type of organisation:

- for universities, NHS organisations or Research Council institutes the processing of personal data for research will be a 'task in the public interest'
- for commercial companies and charitable research organisations the processing of personal data for research will be undertaken within 'legitimate interests'.

For the purposes of the GDPR, the legal basis for processing data for health and social care research is **not "**consent". This means that requirements in the GDPR relating to consent do **not** apply to health and care research.

You should note that if it would be possible to undertake your research without processing personal data then your intended legal basis will not be valid. This means that you should minimise use of identifiable data to the minimum needed for your purpose (see 2.3 on data minimisation).

For paediatric research, the above also applies. The legal basis under GDPR for processing such data for research is the same as above (i.e. public interest or legitimate interests).

Even though consent is not the legal basis for processing personal data for research, the common law duty of confidentiality is not changing, so consent is still needed to access and use confidential patient information for research, unless you have support under the Health Service (Control of Patient Information Regulations) 2002 ('section 251 support') applying via the Confidentiality Advisory Group in England and Wales or equivalent arrangements elsewhere in the UK.

2.2 Transparency

Under the GDPR, transparency relates to providing information to people about the processing of their data. Some of this is addressed at an organisational level in providing public information about use of data. There are important differences between organisations directly receiving information from research participants and organisations receiving information indirectly from another organisation. We will

provide further information to explain direct and indirect receipt of personal data shortly.

Participant data that is no longer identifiable or where the participant cannot be identified directly or indirectly is no longer personal data, and the GDPR transparency requirements do not apply.

This means that your organisation needs to understand what personal data it is currently processing, and will in future be processing, so that it can publish transparency information. You should use the information below to determine what further information, if any, should be given to participants, and how to provide it.

2.3 Safeguards

Safeguards are the measures that are taken to ensure that data is processed securely, accurately and in accordance with data protection principles.

Under GDPR, there is a greater emphasis on implementing safeguards for research. This means that you should give consideration to the arrangements for security and storage of data, and ensure that data are pseudonymised or anonymised wherever possible, and that personal data are only collected when needed (known as 'data minimisation'). If you can undertake some or all of your research activities without using identifiable personal data, you should make arrangements to do so. The UK Policy Framework for Health and Social Care Research provides further safeguards.

For universities, NHS organisations or Research Council institutions relying on public interest as their legal basis, the organisation needs to be assured that any processing of confidential patient information for a research project is in the public interest, eg by being conducted in accordance with the UK Policy Framework for Health and Social Care Research.

2.4 Data subject rights

The GDPR incorporates a range of exemptions from data subject rights for health research, to take account of particular aspects of research. In general these exemptions are similar to those under previous legislation, and mean that normally there will be no right for research participants to access their data, rectify it or have their data erased. However, it is likely that under national policy patients in England will still have a right to opt out of use of their data for research.

The implementation of appropriate safeguards (see section 2.3) permits these research exemptions in relation to data subject rights to be used.

3. What you need to do and what you do not need to do

3.1 Consent

Because you will not be using consent as your legal basis for processing data under GDPR, in most cases you will NOT need to re-consent existing participants (or parents/ representatives for paediatric studies) in order to comply with GDPR. Unless you are making changes to your study processes or arrangements (eg changing what data you collect or how you will hold it), you will not need to re-consent existing participants.

It is important that you are clear that this does not affect the ethical importance of consent. You will also still need to obtain consent for access to or use of confidential patient information to meet the common law duty of confidentiality.

3.2 Transparency

Whatever you may have assumed your legal basis was previously, it is unlikely that you set this out to participants in the Participant Information Sheet for your study. Therefore, in most cases, you will **not** need to correct existing information.

However, under GDPR, in most cases you will need to provide transparency information about your legal basis and other details of processing personal data from 25 May 2018. The table in Appendix 1 sets out the required information that you will need to provide if you collect any new personal data. The table separates out what transparency information you need to provide depending on whether you are collecting personal data directly or indirectly from participants.

This section sets out the options for providing this information and the factors that determine what changes you need to make to your study.

3.2.1 Direct and indirect collection of personal data

For most studies there will need to be transparency information in relation to both the site and the sponsor.

Where possible the sponsor should set out the transparency information relating to both the research activities at sites as well as any processing by the sponsor. Remember, the requirements relate to personal data and not to data that is no longer identifiable or where the participant cannot be identified directly or indirectly. However, to meet ethical and common law expectations, you should still provide clarity to participants about what is happening to their data even when you are not required to provide all the transparency information.

We will publish further guidance on determining whether personal data has been obtained directly or indirectly.

3.2.2 Providing transparency information for new and existing studies

The GDPR requirements for transparency relate to the point of collection of personal data (directly or indirectly) or at the point of change of purpose (e.g. changing use from clinical care to research). This means that the transparency requirements will differ depending on whether you have an existing study at 25 May 2018, or a new

study. For existing studies, what you need to do will also depend on whether the site and/or sponsor will be collecting any more personal data (directly or indirectly), or whether all data has already been collected even if there is processing (e.g. analysis) still to be done. If personal data have already been collected, even if not analysed, then there is no need to provide new transparency information under the GDPR. There may be different situations for different participants in your study.

Importantly, if you do need to provide transparency information, this does **not** mean that you need to amend existing Participant Information Sheets, or submit amendments for approval. You can provide transparency information in a separate document from the Participant Information Sheet. We will shortly be publishing recommended wording for these documents which will allow your amendment to be classed as a **non-substantial, non-notifiable** amendment that does not need to be submitted for approvals, and can simply be implemented. You would then need to include your implemented amendment along with any future amendment submitted for approvals.

Any changes to study documents to update references from previous legislation (i.e. Data Protection Act 1998) to new legislation are classified as **non-substantial, non-notifiable** amendments.

To work out what you need to do, identify the situation below relevant to your study. If you have an existing study, more than one scenario below may apply for different participants. The scenarios below only apply to collection of personal data.

Where you do need to submit an amendment, we recommend that you separate out amendments relating to GDPR from any other amendments to avoid confusion about non-notifiable and notifiable amendments.

A. New study not submitted for approvals before 25 May 2018

Incorporate the recommended wording into your Participant Information Sheet(s) before submitting for approvals.

B. Study approved and recruiting new participants after 25 May 2018

Provide transparency information to new participants using the recommended wording, either as a separate document or by updating the Participant Information Sheet(s). The additional document or revised Participant Information Sheet(s) should be versioned, and you should record that the amendment to your study document is non-substantial and non-notifiable.

If you already have some participants, it may be easier to provide information in a separate document alongside the Participant Information Sheet when you recruit new participants. If you haven't started recruitment, it may be easier for sites if you revise the Participant Information Sheet(s).

C. Study approved and participants are still in the study after 25 May 2018

As participants are still in the study, if personal data is still being collected directly by the site and/or sponsor, you should provide transparency information to these participants when data is next collected directly from them. Use the recommended wording in a separate document if no other aspects of your Participant Information Sheet need to change. You do not need to re-consent existing participants when you provide them with the new transparency information.

If any of the following situations apply you will need to revise your previous Participant Information Sheet(s) as a non-substantial amendment (and submit in the usual way), and re-consent existing participants from whom data is still being collected:

- If you previously told participants that your legal basis for processing personal data was consent (i.e. specifically used the phrase 'legal basis', 'lawful basis' or equivalent) and you are now changing your legal basis and/or
- you are withdrawing any transparency information that you previously told participants and/or
- you are removing any safeguards that you previously told participants and/or
- you are changing any subject rights that you previously told participants and/or
- you are changing the purpose for which personal data are being processed from what you previously told participants

If there will be no further contact with participants, but personal data is still being collected indirectly (eg the sponsor is obtaining existing data from an NHS organisation), you should consider whether you can provide the transparency information through other means. If this could be difficult, there are possible exemptions and you should refer to the HRA's technical briefing notes and seek advice from your organisation.

D. Study approved and participants will have completed the study by 25 May 2018

If no further personal data will be collected directly or indirectly after 25 May 2018, transparency information does not need to be provided to participants, even if you are still processing data eg for analysis.

The HRA will shortly be publishing recommended wording so that you can implement compliant documents as NON-SUBSTANTIAL, NON-NOTIFIABLE amendments.

3.3 Safeguards

In general, the expectations for safeguards should already be being met for research through existing arrangements. Organisations will need to ensure they have safeguards that are compliant, but for researchers the main change will be to review whether there is sufficient data minimisation. For example, this might include ensuring that use of initials and/or date of birth on Case Report Forms is justified.

3.4 Data subject rights

The research exemptions to data subject rights are not automatic, but should be considered on a case by case basis. It is important, therefore, not to offer or limit the rights available to research participants in the Participant Information Sheet, without taking account of the relevance of the rights to a particular project.

If you have previously offered or limited rights to research participants that are not appropriate under GDPR, you may need to revise your previous Participant Information Sheet as a non-substantial amendment (and submit in the usual way), and re-consent existing participants from whom data is still being collected.

4. GDPR and the use of confidential patient information without consent

The Confidentiality Advisory Group (CAG) advises the HRA whether there is sufficient justification to process confidential patient information without consent in England and Wales. Support under the relevant regulations (Health Service (Control of Patient Information) Regulations 2002) sets aside the common law duty of confidentiality. It does not set aside the need to comply with other legislation or the principles of data protection.

This means that there should still be a legal basis as set out above, and that appropriate transparency information should be provided and safeguards implemented. CAG sets certain additional expectations in relation to safeguards (e.g. the opportunity for patients to opt out) and transparency (e.g. patient notification arrangements), which are a condition of the approval for research.

Similarly, where agreement has been obtained for use of confidential patient information without consent by the Public Benefit and Privacy Panel in Scotland, or equivalent arrangements in Northern Ireland, there should must still be a GDPR legal basis for the processing, and transparency information should be provided (where appropriate) and safeguards implemented.

5. Support from your institution

The institution you are working in will be putting arrangements into place for research. Based on their knowledge of your research activities, they may set out special requirements. However, as the information above is applicable to the majority of research, we recommend you draw this guidance to their attention to avoid unnecessary local variations and interpretations.

Appendix 1 – transparency requirements

	Personal data obtained directly from participants	Personal data obtained indirectly
Name of controller and contact details (including of data protection officer)	✓	✓
Purposes of the processing, as well as the legal basis	✓	✓
The categories of personal data concerned		✓
The recipients or categories of recipients of the personal data, if any	✓	✓
The period for which the personal data will be stored	✓	✓
The data subject's rights[2]	✓	✓
The right to lodge a complaint with the ICO	✓	✓
The source from which the personal data originate, and if applicable, whether it came from publicly accessible sources		✓
Whether the provision of personal data is part of a statutory or contractual requirement or obligation and possible consequences of failing to provide the personal data	✓	
Any automated decision-making, and, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject	✓	✓
How appropriate or suitable safeguards are achieved in relation to any personal data transferred out of Europe	✓	✓

[2] For research, under GDPR the basis for processing is not expected to be consent so there is no need to set out the right to withdraw consent at any time