accord
Academic and Clinical Central Office for Research and Development

NHS Lothian

What is GDPR?

The General Data Protection Regulation (GDPR) is the new European-wide law that has been implemented. It comes into force along with the Data Protection Act.

You can read the GDPR document in full here.

When did GDPR come into effect?

GDPR and the Data Protection Act 2018 came into force on 25th May 2018.

What is personal data?

Article 4 of the GDPR regulations state that personal data is any information relating to an identified or identifiable data subject. It further states:

> 'Any 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 number, 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.'

As well as data containing identifiers such as name, date of birth and CHI/NHS number – this includes some genetic and biometric data if unique to an individual. This also includes online identifiers such as IP addresses, mobile data and other online identifiers.

Which studies does this affect?

GDPR will affect all research studies where you are collecting or processing personally identifiable information/data from participants. This includes studies which are actively recruiting participants and also those where recruitment is completed but you are still holding personally identifiable information/data, for example for long-term data linkage.

What do I need to do to comply?

This depends on what category your study falls into.

For more information please read the ACCORD GDPR Important Information.

- If your study was not submitted for approval before 25th May 2018 then you should use the ACCORD Participant Information Sheet and protocol that contains specific wording and advice to make sure your study is GDPR compliant.

- If your study was approved before the 25th May 2018 you should use the stand-alone GDPR participant information template, amend this to suit your study and disseminate appropriately.

GDPR mentions fairness and transparency – how do I achieve this?

To be transparent, information should be provided to the public that is easily accessible. Each study will also have its own specific information. Examples of what should be covered is who the data controller is, why the information is being stored and how it will be processed.

For more about transparency read the HRA information.

Who approves the GDPR participant document?

The stand-alone GDPR participant information template issued by ACCORD does not need to be reviewed by anyone other than your own check to ensure the correct study specific information is included. If any other wording is used this will need to be reviewed by the ACCORD office.

Only this stand-alone document using the template is considered a non-substantial, non-notifiable amendment.

If you are still unsure about any aspect of document content please contact the ACCORD office: resgov@accord.scot for further advice.

This information should be included as part of any future amendment to ensure that any approving bodies are aware.

Who do I need to issue this information to?

All participants whose personal data is being held as part of a study should receive the transparency information. This includes participants who are active on the study and those who have completed the study but with whom you are still processing/holding personal data for.

How should I disseminate this information?

You can disseminate the transparency information in a variety of ways. These include, but are not restricted to:

- In appointment and clinic letters
- Providing at the participants next study visit
- Organisation/unit/study websites
- Social media e.g. Facebook, Twitter
- Posters and leaflets in clinic
- Study-specific materials

When do I have to complete this by?

You should aim to provide participants with relevant transparency information as soon as possible, but do not panic. We appreciate that it will take time to put this information together and would look to you providing participants with the information by the first week of July 2018. ACCORD will provide reminders after this time if you have not contacted us to confirm completion.

What resource is available to me?

As Investigator for the study you are responsible for compiling the transparency information in order for your study to comply with GDPR. To help with this ACCORD have provided a stand-alone GDPR participant information template as well as template wording for general participant information sheets.

Stand-alone GDPR Participant Information Template

General Participant Information Sheet Template (CR007)

You can also contact us at the ACCORD office: resgov@accord.scot if you need further advice.

I have been told to contact my Sponsor for further GDPR information, who is the Sponsor of my study?

The Sponsor is the organisation that takes responsibility for your study. If your project is an academic study and you are an employee or student of either University of Edinburgh or NHS Lothian it is likely that University of Edinburgh and NHS Lothian sponsor your study.

University of Edinburgh and NHS Lothian work jointly in the ACCORD office.

If you are unsure who the Sponsor is you can check A64 of your IRAS form if you have one or contact the ACCORD office: resgov@accord.scot who can check for you.

What happens if my study is not sponsored by University Edinburgh/NHS Lothian?

If your study is not sponsored by University of Edinburgh and/or NHS Lothian, you should contact the organisation that is listed as your Sponsor for further advice about how GDPR should be implemented.

My study was approved prior to 25th May 2018, do I need to re-consent all my participants?

No, there is no need to re-consent existing participants when providing them with the new transparency information.

My study does not need NHS ethics and/R&D approval – what do I have to do?

GDPR is independent of ethics/R&D/MHRA.

If your study uses personal data, regardless of whether NHS ethics and/or R&D approval was not required, you are still required to comply with GDPR.

My study involves anonymous data linkage only – do I need to do anything?

No, if your study is truly anonymised you are not using personal data and GDPR does not apply.

Anonymisation should conform to the ICO Anonymisation Code of Practice.

Does pseudo-anonymised/link anonymised data count as anonymised data?

No, only data that has been irreversibly anonymised does not count as personal data.

Pseudoanonymisation/link anonymisation is not the same as anonymisation and remains as personal data.

If the link to de-anonymise the data is kept within the same organisation this is considered personal/identifiable data.

Anonymisation should conform to the ICO Anonymisation Code of Practice.

My study involves genetic data what do I need to do?

GDPR includes genetic information in its definition of personal data. Genetic data is also considered to be a 'special category of personal data' and therefore is considered more sensitive and in need of additional protection.

To process this data lawfully you must have a legal basis. When processing special categories of personal data, your legal basis is that this is 'necessary for scientific research purposes in accordance with safeguards'.

My study is sponsored by University of Edinburgh/NHS Lothian but has a commercial collaboration – what should I do?

If any personal/identifiable information is being transferred to a commercial company, you will need to inform participants of this transfer and state what data is being transferred, the safeguards in place to protect the data and seek explicit consent (naming the company involved) from each participant.

My study involves transferring personal data/link anonymised data outside the UK, what do I need to do?

GDPR poses restrictions on the transfer of personal data outside the European Union. If you plan to transfer data or link anonymised data outside the UK please contact the ACCORD Office: resgov@accord.scot for specific advice.

My study has international sites-what should I do?

If your study involves international participants or international sites and University of Edinburgh and/or NHS Lothian are the Sponsor you are still required to comply with GDPR. The implications of GDPR extend to all participants and sites involved in the study.

Where can I go for further information?

For further information or help please contact:

ACCORD: resgov@accord.scot

Other useful resources

ACCORD website

ACCORD GDPR Important Information

MRC Regulatory Support Centre Blog GDPR: What researchers need to know

HRA Guidance on GDPR

ICO Guide to GDPR