Norfolk and Suffolk
NHS Foundation Trust

Managing your information

A guide for research participants

A full version of this document can be found on our website www.nsft.nhs.uk

Norfolk and Suffolk NHS Foundation Trust (the Trust) provides mental health care services to the residents of Norfolk and Suffolk.

Our services include mental health, learning disabilities, eating disorders and wellbeing.

The Trust is registered with the Information Commissioners Officer as a Data Controller.

This privacy notice only relates to the personal data of research participants or potential participants and is a summary of our main online trust wide privacy notice (www.nsft.nhs.uk) which sets out in full the Trusts lawful bases for processing your personal data and all of your rights as data subjects under the GDPR and the DPA18.

Patient Information and health and care research

All NHS organisations (including Health & Social Care in Northern Ireland) are expected to participate and support health and care research. The Health Research Authority and government departments in Northern Ireland, Scotland and Wales set standards for NHS organisations to make sure they protect your privacy and comply with the law when they are involved in research. Research ethics committees review research studies to make sure that the research uses of data about you are in the public interest, and meet ethical standards.

Health and care research may be exploring prevention, diagnosis or treatment of disease, which includes health and social factors in any disease area. Research may be sponsored by companies developing new medicines or medical devices, NHS organisations, universities or medical research charities. The research sponsor decides what information will be collected for the study and how it will be used.

Health and care research should serve the public interest, which means that research sponsors have to demonstrate that their research serves the interests of society as a whole.

They do this by following the UK Policy Framework for Health and Social Care Research.

They also have to have a legal basis for any use of personally-identifiable information.

What is personally-identifiable data?

Under Article 4 of the GDPR '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

Under Article 9 of the GDPR 'Special Categories of Personal Data' means:

- Personal data that relates to race, ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetics, biometrics (where used for ID purposes), health, sex life or sexual orientation

Lawful Bases for processing personally-identifiable information for research purposes

Article 6 (1) (e):

- 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 9 (2) (j):

- Necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89 (1) 'subject to appropriate safeguards that ensure technical and organisation measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner'

Section 251

Section 251 of the NHS Act 2006 allows the common law duty of confidentiality with regard to patient information to be set aside in specific circumstances, where anonymised information is not sufficient and where patient consent is not practicable. This legislation provides for the use of confidential patient information for medical research purposes under strict guidelines.

Consent

Historically research studies that involved personally-identifiable information have obtained consent and/or assent from participants (whether direct or through consultees/representatives), to meet ethical expectations and avoid a breach of the common law duty of confidentiality. This requirement has not changed under the GDPR.

Consent is still needed for people outside the care team to access and use personally-identifiable information for research, unless section 251 support is in place.

For the processing of health and care personal data for research purposes to be legal, the following criteria must be satisfied:

- The GDPR lawful basis must be identified
- The common law duty of confidentiality must be met through consent (this does not apply if section 251 support is in place)

Consent is not our legal basis for processing your personal data for research purposes

Common Law – confidentiality

Information is considered confidential in law if:

- It is not in the public domain
- It can be related to an identifiable individual (both living and deceased)
- It has a degree of sensitivity associated with it
- It is given with the expectation that it will be kept confidential (the common law of confidentiality does allow us to share confidential information in relation to crime and safeguarding, when in the overwhelming public interest)

Reasonable Expectations

When confidential information is given to a clinical team and/or a research team, it will be handled in line with 'reasonable expectations'. Collaboration between clinical teams and research is common place and we will tell you what our intentions are in relation to your information to ensure you understand what is proposed and what it means for you.

Data will be anonymised where possible.

Disclosure of information outside reasonable expectations to support research

We are able to disclose your information outside of reasonable expectations if we have 'Section 251' approval to do and such disclosure is approved by the Health Research Authority (www.hra.nhs.uk). This does not affect our obligation to abide by the GDPR and DPA18.

If we disclose personal data under 'section 251' both recipient and disclosing organisations will:

- Have a legal basis to hold and use the data (both personal and special categories)
- Be fair and transparent about holding and using the data – patient notification will be issued

National patient opt-out programme and the common law of confidentiality

This opt-out only applies to the common law of confidentiality and not the GDPR and DPA18 and should not be confused with the GDPR Right to Object.

Further information regarding the national opt-out can be found at www.digital.nhs.uk

Safeguards

- Processing personal data for research purposes will not cause distress or damage to someone and will only be processed in the public interest
- Only the absolute minimum amount of personal data required for research will be used
- Data will be pseudonymised where compatible with the achievement of the research purpose
- Where the research purpose can be satisfied by processing anonymised data, identifiable data will not be used
- Suite of Information Governance Policies are in place together with the use of the common law duty of confidentiality to ensure your data is adequately protected and processed in accordance with the law

How patient information may be used for research

When you agree to take part in a research study, the sponsor will collect the minimum personally-identifiable information needed for the purposes of the research project. Information about you will be used in the ways needed to conduct and analyse the research study.

NHS organisations may keep a copy of the information collected about you. Depending on the needs of the study, the information that is passed to the research sponsor may include personal data that could identify you.

You can find out more about the use of patient information for the study you are taking part in from the research team or the study sponsor. You can find out who the study sponsor is from the information you were given when you agreed to take part in the study.

For some research studies, you may be asked to provide information about your health to the research team, for example in a questionnaire.

Sometimes information about you will be collected for research at the same time as for your clinical care, for example when a blood test is taken.

In other cases, information may be copied from your health records. Information from your health records may be linked to information from other places such as central NHS records, or information about you collected by other organisations. You will be told about this when you agree to take part in the study.

Keeping information for future research

Information about you that is collected during a research study may be kept securely to be used in future research in any disease area, including research looking at social and economic factors affecting health. This may include combining it with information about you held by other health or government organisations such as NHS Digital. Usually the information is combined together by matching information that has the same NHS number. Doing this makes maximum use of the information you have provided and allows researchers to discover more.

Researchers may not be able to specify all the possible future uses of the information they keep. It could include providing the information to other researchers from NHS organisations, universities or companies developing new treatments or care. Wherever this happens it will be done under strict legal agreements. The information about you will be depersonalised wherever possible so that you cannot be identified. Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

On rare occasions NHS organisations may provide researchers with confidential patient information from your health records when we are not able to seek your agreement to take part in the study, for example because the number of patients involved is too large or the NHS organisation no longer has your contact details. Researchers must have special approval before they can do this.

Your choices about health and care research

If you are asked about taking part in research, usually someone in the care team looking after you will contact you. People in your care team may look at your health records to check whether you are suitable to take part in a research study, before asking you whether you are interested or sending you a letter on behalf of the researcher.

In some hospitals and GP practices, you may have the opportunity to sign up to a register to hear about suitable research studies that you could take part in. There are also national databases (such as Join Dementia Research) on which you can register. If you agree to this,

then research nurses, researchers or administrative staff authorised by the organisation may look at your health records or register records to see if you are suitable for any research studies.

It's important for you to be aware that if you are taking part in research, or information about you is used for research, your rights to access, change or move information about you are limited. This is because researchers need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from a study, the sponsor will keep the information about you that it has already obtained. They may also keep information from research indefinitely.

If you would like to find out more about why and how patient data is used in research, please visit the Understanding Patient Data website.

Further information is available, depending on where in the UK you live:

- **England -** In England you can register your choice to opt out via the NHS website. If you do choose to opt out you can still agree to take part in any research study you want to, without affecting your ability to opt out of other research. You can also change your choice about opting out at any time.

Data Controllers in health and care research

- The sponsor of the research study acts as the data controller in relation to the research data
- If you are a service user, the same information may be provided to your care team. In this case, the organisation is also the controller
- If the purpose of collecting the data was the delivery of your healthcare and you are not participating in a research study, then the Trust is the controller
- If the data is then transferred to a research sponsor, the sponsor has obtained it indirectly and becomes the controller for the processing of the data for research purposes

Further information regarding the controller of your research data can be obtained from your research team.

What to do if there is a problem

If you wish to raise a complaint on how any research organisation has handled your personal data, you can contact the relevant Data Protection Officer who will investigate the matter. If you are not satisfied with their response or believe they are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Trust contacts

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