This is what Spectrum 10K has said about:
Questionnaires and medical records

Contents

1. Why does Spectrum 10K need questionnaires (including those addressing sensitive issues)?

Questionnaires are helpful because they can help us obtain information about a person's/child's life directly from them or their carer. The questionnaires used in Spectrum 10K cover many aspects that impact the lives of autistic people.

The registration questionnaire for Spectrum 10K includes questions about mental health, physical health, lifestyle, and autistic traits. We also ask these questions about non-autistic relatives so that we can compare information obtained from autistic people with their non-autistic relatives. This will help us to understand what is unique to autistic people and what is shared among family members.

Optional questionnaires have been carefully selected to ask questions about autism that we think will be valuable to autistic people. For example, one questionnaire covers the under-studied topic of sensory sensitivity differences.

Some of the optional questionnaires include sensitive questions related to mental and physical health. While some include potentially distressing topics such as experience of child abuse or feelings of suicide, which participants may find upsetting, we believe it is important to study these topics. Asking questions about suicide may lead to ways of helping people in the future. We will always warn participants about potentially distressing questions and provide information about where to seek help if they do become distressed. These are optional questionnaires and participants have the option to opt out completely or skip individual questions they are not comfortable answering.

The more information we analyse, the better we will be able to understand the diversity of experiences within autism and co-occurring physical and mental health conditions.

2. Why do you need access to my medical health records (also called electronic health records or NHS health records)?

One of the aims of Spectrum 10K is to identify genetic and environmental factors that impact on the physical and mental health of autistic people. To achieve this aim, we need to collect information about participants' co-occurring health conditions.

There are two ways we can collect information about co-occurring health conditions:

- Through questionnaires
- Through medical health records (Electronic Health Records) held in the NHS.

We will be able to collect some information about co-occurring health conditions through our questionnaires, which participants will complete when they sign up to participate in Spectrum 10K. However, our questionnaires may not cover all co-occurring health conditions, especially rare conditions.

We can also collect information about co-occurring health conditions by accessing information about participants' diagnoses, prescribed medications, hospitalisations, referrals, and test results from their Electronic Health Records, which are held by the NHS. We set this out within the Spectrum 10K grant application to the Wellcome Trust. A combination of information collected from questionnaires and Electronic Health Records can provide more complete information of someone's health than using either one of them alone.

By analysing participants' genetic and questionnaire data alongside this information from their Electronic Health Records, we will be better able to understand the relationship between genes, co-occurring health conditions, and health outcomes.

We are requesting access to participants' Electronic Health Records because many other research studies have shown how useful this information can be. For example, other researchers have recently used Electronic Health Records to identify groups who are more vulnerable to long COVID or more likely to develop dementia. This makes it easier for health and social care services to support these groups. We would like to do the same for groups of autistic people who might be more likely to have or develop co-occurring health conditions.

3. How will you access my medical records?

Your medical records (Electronic Health Records) will be accessed through applications to national bodies who are responsible for data governance and access. There are strict data sharing protocols which are overseen and authorised by national bodies in England, Wales, Scotland and Northern Ireland. Particular organisations oversee and are responsible for governance of data access and applications. In some circumstances, though not always separate organisations oversee the data sharing process. For example: **NHS Scotland** Public Benefit and Privacy Panel for Health and Social Care **(HSC-PBPP)** is a governance structure of NHS Scotland (NHSS) who scrutinise and approve an application. Data access is managed and overseen by electronic Data Research and Innovation Service (**eDRIS**), whose team are part of Public Health Scotland.

Once an application has been completed, submitted to the relevant application body and approved, a signed data access agreement is put in place. Data is then shared electronically via secure Safe Havens. Health records are accessed using participants' personal details and/or their NHS number. Only one person in the Spectrum 10K team will be able to link your DNA and questionnaire data to your NHS data. This is the database manager. As soon as the data has been linked in the Spectrum 10K database, the information is pseudonymised.

Can researchers see entire health records?

No. The Spectrum 10K team will only access the relevant sections of participants' health records. Researchers will make a request, for example asking about additional diagnoses or medication, a data manager at the National Digital Health organisations will then find and extract that information and share *only that information* with researchers.

Is it unusual for researchers to access health records?

Accessing health records in this way is not unique to Spectrum 10K. Many research studies and databases have linked to medical health records to provide crucial information on health. For example, a recent study used medical health records to understand who are more vulnerable to long COVID (Millions of GP records provide vital insights into long COVID (digitalhealth.net).

Similarly, using medical health records, researchers have been able to identify those who are more likely to develop dementia (Electronic health records-based tool uses data to detect undiagnosed dementia | National Institute on Aging (nih.gov))

For further information on the national organisations responsible for governance and data access in England, Wales, Scotland and Northern Ireland, please see the following:

England:

NHS England is the custodian for health and care data for England. Applications to link health data are submitted to the Data Access Request Service (DARS) within NHS England.

Information about how NHS England protects your data can be found here:

https://digital.nhs.uk/data-and-information/keeping-data-safe-and-benefitting-the-public/how-we-look-after-your-health-and-care-information

Information about NHS England and the Data Access Request Service can be found here:

https://digital.nhs.uk/services/data-access-request-service-dars/how-nhs-digital-makes-decisions-about-data-access

https://digital.nhs.uk/services/data-access-request-service-dars#further-information

Wales:

SAILS is a Trusted Research Environment (TRE), which is a safe, secure, computing environment where researchers, scientists and other experts can gain access to data for research in the public interest, via a rigorous approval process. It is funded by Health and Care Research Wales through the Welsh government.

The Information Governance Review Panel (IGRP) provides independent guidance and advice on Information Governance policies, procedures and processes for SAIL Databank. All applications to use the SAIL database are overseen by the Information Governance review panel (IGRP)

Information about data management policies within SAIL can be found here:

https://saildatabank.com/governance/approvals-public-engagement/information-governance/

https://saildatabank.com/about-us/policies/

Scotland:

As mentioned above, **NHS Scotland** Public Benefit and Privacy Panel for Health and Social Car**e (HSC-PBPP)** is a governance structure of NHS Scotland (NHSS) who scrutinise and approve applications to health data. Data access is managed and overseen by the electronic Data Research and Innovation Service (**eDRIS**), whose team are part of Public Health Scotland.

Information about the governance role of HSC-PBPP can be found here:

https://www.informationgovernance.scot.nhs.uk/pbpphsc/

The privacy policy of Public Health Scotland can be found here:

https://www.publichealthscotland.scot/our-privacy-notice/organisational-background/

Northern Ireland:

Within Health and Social Care Northern Ireland (HSCNI), the Honest Broker Service (HBS) is responsible for Information Governance and access to anonymised data for ethically approved research.

Secure access to de-identified data via a safe setting is via the Health Data Research Northern Ireland UK Secure e-Research Platform (HDRNI UK SeRP) which was established in March 2021.

Further information about the privacy policy of the Honest Broker Service can be found here:

https://hscbusiness.hscni.net/pdf/HBS_Privacy_Notice_Feb21.pdf