

**Consultee Information Sheet**  
Study Title: Spectrum 10K

REC Ref: 20/LO/0873  
IRAS Ref: 266324

**Introduction**

**You are being invited to consider giving your advice for the individual under your care to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve.**

**We will ask that you put your own views about the research aside and to consider and take into account, the past and present wishes and feelings of the individual you are advising for, had they been able to consent for themselves.**

**Please take time to read the following information carefully and discuss it with others if you wish.**

**We will understand if you do not want to take on this responsibility. If you do not wish to act as a consultee your legal rights will not be affected in any way.**

**If you decide that the individual you would advise for does not wish to take part it will not affect the standard of care they receive in any way.**

**Please contact the Spectrum 10K team if there is anything that is not clear or if you would like more information.**

**Thank you for reading this.**

## **1. About Spectrum 10K**

### **1.1 What is the purpose of the study?**

Spectrum 10K aims to recruit at least 10,000 individuals with a diagnosis of Autism Spectrum Conditions (hereafter ‘autism’) and, where possible, their relatives to identify genetic and environmental factors that contribute to autism and related conditions.

Spectrum 10K is funded by the Wellcome Trust and is being led by a team of researchers at the Autism Research Centre at the University of Cambridge, the Wellcome Sanger Institute and the University of California Los Angeles (UCLA).

Signing up to Spectrum 10K (at [www.spectrum10k.org](http://www.spectrum10k.org)) will involve giving advice on whether or not the individual under your care would like to take part, completing a brief questionnaire to confirm that the person under your care lacks mental capacity, completing questionnaires on their behalf, collecting their saliva sample, and giving permission to obtain their medical records (to investigate important clinical information relevant to the study). Participation in this study is completely voluntary. You can withdraw the individual at any time without giving a reason.

## **2. Taking Part in Spectrum 10K**

### **2.1 Why have we invited the individual you are advising for to participate?**

The individual you are advising for has been asked to take part because you have seen the study advertised in the press and/or on social media, or have been invited by their relative, or have been approached by their clinician, and you have indicated that the individual you are advising for:

- Is aged 16+ and has been diagnosed with autism.  
OR
- Is aged 16+ and is biologically related to an autistic adult or child who is participating in Spectrum 10K (up to third-degree: parent, sibling, child, aunt, uncle, niece, nephew, grandparent, grandchild, half-sibling, first cousin, great-grandparents).

The person under your care currently lacks the capacity to make an informed decision about whether to join the Spectrum 10K study at this time. We will ask you as their carer to act as their consultee and give your advice concerning their participation.

### **2.2 Do they have to take part?**

No. It is up to you to decide whether the individual takes part in the research or not. If you decide that they can take part you are free to withdraw them from Spectrum 10K at any time and without giving a reason and, and without the individual’s medical care or legal rights being affected.

## 2.3 What will happen to the individual you are advising for if they take part in the research?



Participation in Spectrum 10K will not form part of standard care/ hospital /clinic appointments. Participation can take place in your own home as long as you have access to a computer. If you have been approached through a local clinic, a member of their team may help provide support to complete the study steps.

**Step 1- Registration:** If you have decided that the individual you are advising for would be happy to participate in the study, please register him/her at [www.spectrum10K.org](http://www.spectrum10K.org). You will be asked to complete the following:

- **Declaration:** You will be asked to sign a consultee declaration form and advise on the individual under your care. Once signed, the declaration form will be available to download for your records.

Some of the items on the declaration form are optional. If you decide to opt out of any optional items, the individual you are advising for will not be excluded from the study, however all other consent points are required for study participation.

- **Participant Information:** You will be asked to provide the name, date of birth, information about their autism diagnosis (if applicable), and demographic information of the individual you are advising for. We will also ask for the contact email address and the postal address to send the saliva kits to (if needed) for the individual on whose behalf you are advising . This may be your address.

We will also ask you to provide, if possible, the NHS number of the individual you are advising for to link to their Electronic Health Records. Please see below for more information about collecting information about medical records.

- **Clinical Report (If Applicable):** If the individual you are advising for has an autism diagnosis from a qualified professional, you will be asked to upload a copy of their clinical report with information regarding their diagnosis (only the page that confirms the diagnosis). If you do not have an electronic copy, you may upload a photographed or scanned copy, as long as it is legible. This diagnostic report will be uploaded into a secure database that can only be accessed internally by approved Spectrum 10K research personnel.

Alternatively, you can provide a paper copy of their clinical report. We will provide you with a pre-paid return envelope if you choose this option.

This is not mandatory and will just enable us to obtain more information about their autism diagnosis.

- **Sign-up Questionnaire (Baseline Questionnaire):** You will be asked to complete a sign-up questionnaire on behalf of the individual you are advising for. This includes questions about their health, lifestyle, education and questions related to autistic traits. This will need to be completed even if the individual you are advising for does not have a diagnosis of autism. This should take no longer than 15-20 minutes.
- **Coronavirus Questionnaire (Optional):** We want to understand the impact of COVID-19 on the autism community. At baseline, you will be provided with the option to complete an additional COVID -19 questionnaire on behalf of the individual you are advising for. This is optional and will not stop the individual you are advising for from participating in Spectrum 10K if it is not completed. The questionnaire will ask about whether the individual you are advising for was unwell due to COVID-19 or knew a person who was, symptoms they experienced, treatment management and shielding. It will also ask about the impact of COVID-19 on their finances, mood and anxiety levels. This usually takes 25 – 30 minutes. If you choose to complete the COVID-19 questionnaire on behalf of the individual you are advising for, we will ask you to repeat the questionnaire every 3 months for 2 years. This is so we can study the long-term effects of the pandemic on autistic individuals and their families. You will receive an email reminding you to complete the questionnaire when it is due.

**Step 2 - Saliva DNA Kit:** We will send a spit tube that you will use to collect the individual’s saliva sample, instructions on how to do so will be included along with pre-paid return envelopes. This will be sent to the address you provide. We will extract DNA from their sample. If you are at an NHS Trust site when registering the individual, the research care team will be able to help you collect their saliva sample.

To use the saliva kit all the individual will need to do is spit into the tube. If this might be difficult to complete, we have assisted saliva collection kits. You will have the option to request the assisted saliva collection kit during registration. If you are at an NHS Trust site when completing this, the research care team will be able to provide you with an assisted kit.

**Step 3 - Optional Questionnaires:** You will have the option to log into your Spectrum 10K account (at [www.spectrum10k.org](http://www.spectrum10k.org)) and complete additional questionnaires on behalf of the individual you are advising for. There are 3 sets (or phases) of optional questionnaires for participants without capacity. Each phase usually takes 20-25 minutes to complete. You can complete these all at once, or save your progress and complete these in your own time. We will send you a maximum of 4 reminder emails for each set of questionnaires over a period of 24 months after the initial registration.

Optional questionnaires will include sensitive questions related to the mental and physical health of the person you are advising for and include potentially distressing topics such as abuse and suicide which you or the person you are advising for may find upsetting. If you decide to complete these questionnaires, you will have the option to stop at any time, refuse to answer individual questions, or skip entire questionnaires altogether. You may also wish to consider who is present when you are completing these to ensure that you are comfortable doing so.

## 2.4 Can other family members participate in the Spectrum 10K study?

Yes, if the individual you are advising for is a primary participant (i.e. has a professional autism diagnosis), their biological relatives can be invited to participate in Spectrum 10K (up to third-degree). Third degree eligible relatives include; biological parents, biological children, biological (half or full) siblings, biological aunts or uncles, grandparents, first cousins and great-grandparents of the primary participant.

If the individual you are advising for is not a primary participant (i.e. they do not have an autism diagnosis), then you will not be eligible to invite these relatives.

If eligible, you will need to specify the relationship of the individual to each relative and enter their email address. Relatives will receive a URL link which will direct them to register online. Using this URL method will allow for relatives to be automatically linked to the individual you are advising for. We will not collect any personal information about relatives at this point and the email address will not be visible to us.

Relatives who are invited to participate in the study must complete their own online registration form, including consent and will be asked to provide their own saliva sample. All child relatives must be registered by a parent or legal guardian.

### **2.5 Will I or the individual I am advising for be paid?**

Unfortunately, we are not able to pay you or the individual under your care for your or their participation in this study.

### **2.6 Will I or the individual I am advising for be re-contacted?**

To better understand co-occurring conditions in autism and wellbeing, we may need to recontact you to invite the individual you are advising for to participate in other ethically approved studies. Their participation in any such other studies is entirely voluntary - you can decide at the time. They will receive a maximum of 4 invitations per year to participate in other studies.

## **3. Data Use, Storage, and Safety**

### **3.1 Summary**

We will need to use information from the person you are advising for and their medical records for this research project. This information will include their name, date of birth, NHS number, gender and postcode. People will use this information to do the research or to check their records to make sure the research is being done properly.

People who do not need to know who they are will not be able to see their name or contact details. Their data will have a code number instead. We will keep all information about the person you are advising for safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that they took part in the study.

The person you are advising for can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have. We need to manage their records in specific ways in order for the research to be reliable. This means that we won't be able to let you see or change the data we hold about the person you are advising for. If the person you are advising for agrees to take part in this study, they will have the option to

take part in future research using their data saved from this study. You can find out more about how we use their information at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)

### **3.2 Will you have access to medical records?**

One of the aims of Spectrum 10K is to identify factors that contribute to co-occurring physical and mental health conditions in autistic individuals. As part of this study we will apply for permission from the national dataset bodies to view participant electronic health records (EHRs). We will obtain health-related records and prescribed medicines held by the NHS General Practices and Hospitals of the individual you are advising for. This includes information about any diagnoses the individual may have, hospitalization records, and test results (such as blood test and scan results). From these, we will obtain a full understanding of the relationship between autism related genes, co-occurring conditions, medical care and outcomes. It will also help us to identify where current needs of autistic individuals and their families are not being met.

We will use details such as NHS number or equivalent, date of birth, name, gender and postcode to identify medical records. Data from these records will be shared with the Spectrum 10K research team and stored long-term. These data will be held under a unique study number assigned to the individual you are advising for, with all personal identifying information removed (i.e. pseudonymised). Contact details will be held in a separate database not linked to medical information or to the research data we hold about the individual you are advising for.

An application will be made to the national bodies NHS Digital (England), SAIL database (Wales), NSS/eDRIS (Scotland), HSC Trust (Northern Ireland) who act as data controllers, and who hold and maintain medical records and national datasets. For further information on the privacy policy of these organisations, please see the following:

NHS Digital: <https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe/how-we-look-after-your-health-and-care-information>

SAIL Databank: <https://saildatabank.com/saildata/data-privacy-security/>

eDRIS: <https://www.isdscotland.org/Products-and-Services/eDRIS/How-eDRIS-is-Secure/>

NSS: <https://nhsnss.org/how-nss-works/policies-and-statements/privacy-advisory-committee/>

HSCNI: <https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/hsc-security-policy.docx>

### **3.3 What will happen to the information of the individual I am advising for and how will you keep their data safe and confidential?**

Once the steps are completed to sign up to Spectrum 10K, the information of the individual you are advising for will be stored within the Spectrum 10K database. Their data will be stored long-term by Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) and the University of Cambridge for use in current and future ethically approved research aimed to better understand autism, other co-occurring conditions, and wellbeing.

The data you provide for the individual you are advising for will be kept strictly confidential. All of their personal information will be stored on secure servers located at the University of Cambridge, and will only be accessible by approved researchers from the Spectrum 10K study. All data shared with collaborators will be anonymised, meaning that the individual you are advising for will not be identified from any of the samples or data provided. The pseudonymised medical and health data of the individual you are advising for will be stored separately from their personal details. All data collected will be collected in line with the Data Protection Act 2018 and GDPR (General Data Protection Regulations). Data collection will also comply with the Common Law Duty of confidentiality.

CPFT and the University of Cambridge are joint sponsors for this study based in the United Kingdom. CPFT and the University of Cambridge will use information about the individual you are advising for and their medical records in order to undertake this study and will act as the data controller. This means that they are responsible for looking after the individual's information and using it properly. With your permission, CPFT and the University of Cambridge will store identifiable and non-identifiable information long term. Information will be stored until you withdraw the individual you are advising for.

Your rights to access, change or move the individual's information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. To safeguard the rights of the individual you are advising for, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at: <https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/>

### **3.4 What will happen to the saliva sample of the individual I am advising for?**

The anonymised saliva sample of the individual you are advising for will be delivered to a laboratory to extract DNA for genetic analyses. We may analyse all or parts of the individual's DNA. Their DNA sample will be stored long-term.

### **3.5 What will the individual's DNA be used for?**

We will use the individual's DNA to search for structural and functional changes in the DNA that may contribute to autism and related conditions. This will be done by analysing either their entire DNA code or only parts of their DNA code. We may also investigate how genes are switched on or switched off, a process known as epigenetics. We are happy to describe this in detail should you need more information on this.

### **3.6 Who will analyse the data of the individual I am advising for?**

The genetic and clinical data of the individual you are advising for will be analysed by a member of the Spectrum 10K research team or a trusted academic collaborator for ethically approved research.

### **3.7 Will data of the individual I am advising for be shared with academic researchers outside Spectrum 10K?**

We may share the anonymized (genetic and questionnaire) data of the individual you are advising for using highly secure research databases (repositories) or share with potential

academic collaborators for future research. We will not share any personal information with other researchers.

### **3.8 Will data of the individual I am advising for be shared with commercial collaborators?**

In some instances, Spectrum 10K may also share anonymised data with commercial collaborators. This is optional, and you can indicate if you would like the data of the individual you are advising for to be shared. Any commercial collaboration will be in line with the aims of Spectrum 10K. Some examples of such collaborations may include developing a drug for a specific type of epilepsy or gut difficulties relevant to some autistic individuals, or developing an algorithm to better detect depression in autistic individuals. Such research is typically conducted in commercial collaboration.

### **3.9 What if the individual I am advising for does not want to continue in the study?**

If you think the individual you are advising for would no longer wish to take part in the study, or you would like to stop acting as a consultee, you are free to withdraw them from Spectrum 10K at any time. You do not have to give a reason and the care provided to the individual you are advising for will not be affected in any way.

You are welcome to discuss concerns with us at any time, and the various options you have for withdrawal. Please contact the Spectrum 10K team by phone on 0800 052 0050 or email the team at [info@spectrum10k.org](mailto:info@spectrum10k.org).

You have three options for the withdrawal of the individual you are advising for:

#### **No Further Contact:**

This means that Spectrum 10K would no longer contact you directly but would have permission to retain and use information and samples provided previously by the individual you are advising for, and to obtain and use further information from their health records. This level of withdrawal allows researchers to study autism with the goal of improving the health of people with autism and their family members.

#### **No Further Access:**

This means that Spectrum10K would no longer contact you or obtain further information from the health records of the person you are advising for in the future; but still has permission to use the information and samples provided previously.

#### **No Further Use:**

In addition to no longer contacting you or obtaining further information, any information and samples collected previously would no longer be available to researchers. Spectrum 10K would destroy the sample of the person you are advising for (although it may not be possible to trace all distributed sample remnants) and would only hold information for archival audit purposes. Such a withdrawal would prevent information about the person you are advising for, from contributing to further research, but it would not be possible to remove data from research that had already taken place

### **3.10 What will happen if the person I'm advising for regains capacity?**



If your person you are advising for regains capacity during the course of the study, we ask you to please email us at [info@spectrum10k.org](mailto:info@spectrum10k.org) to let us know and they will be asked to give their consent to continue in the study.

Any saliva sample provided or questionnaires you have completed on behalf of the person you are advising for will be retained as part of their data collection within the study. If they regain capacity, any subsequent questionnaires/saliva sample that they provide will be added to this.

You will be directed to enter an email address for the participant who regains capacity. We will not collect any personal information about the person who regains capacity at this point; the email address will not be stored and will not be visible to us.

The person who regains capacity will receive a URL link which will direct them to register online. The account will be frozen at this point and you will no longer have access. The account will only be reactivated when the participant who regains capacity accesses the account and decides if they wish to continue in the study.

### **3.11 Who has reviewed the study?**

Spectrum 10K has been reviewed and a favourable opinion was given by independent ethics review committees at London Queens Square REC and Scotland A-REC.

## **4. Advantages and Disadvantages**

### **4.1 What are the possible benefits of taking part?**

The individual you are advising for will not benefit directly from taking part in this study. However, the information we gain from this study will help to further our understanding of the relationship between genes, autism and related conditions. This research may lead to improved quality of care for autistic individuals and their families.

### **4.2 What are the possible disadvantages and risks of taking part?**

1. Providing a saliva sample is a very low risk procedure but may be unpleasant for some people. We will offer foam swabs to aid the collection of saliva to participants who cannot produce enough saliva through spitting. You will have the option to request the assisted saliva collection kit during registration.
2. Our questionnaires may cover topics which some people might find sensitive, and about difficult lived experiences of mental or physical conditions. Although this relates to the individual you are advising for, this may affect you too. You will have the option to skip some questions by selecting the 'I prefer not to answer' option.
3. The participation of the individual you are advising for is strictly confidential. Where appropriate, we may share their anonymised data in highly secure research databases or share with potential collaborators. The risk of identifiable information being accidentally disclosed is extremely low.

### **4.3 Will Spectrum 10K provide feedback about the genetic results of the individual I am advising for?**

We understand that some autistic individuals and their family members (or carers) would like to receive feedback about their DNA. However, we do not currently have the facilities to provide feedback on individuals' genetic data in an ethical manner that minimizes distress with the right support and counselling services. For this reason, we are currently unable to provide feedback on genetic data. However, we may consider developing an infrastructure to do so in the future. If this becomes possible, we will contact all participants in the future requesting consent to provide feedback about their genetic data.

However, the individual you are advising for may be eligible for genetic testing in certain situations. These may include having a developmental delay, a learning disability, and congenital abnormalities. If you think they might be eligible for genetic testing, please consult their GP to find out how to get a referral.

### **4.4 Will you contact the GP of the person I am advising for?**

In some exceptional circumstances, we may need to contact the GP of the person you are advising for to inform them about their participation in the study and any important information related to their health and safety that we hold about them. This will occur only if we find something that may affect their clinical care. Please note, we will not be contacting their GP routinely to inform them about the participation in the study nor will we be routinely feeding back any information you provide us to the GP of the you are advising for.

## **5. Final Details**

### **5.1 Will we be in contact during this study?**

As part of Spectrum 10K, we will send reminder emails and updates about the participation and progress of the individual you are advising for.

Additionally, you will be given the option to subscribe to our newsletter. If you are interested in receiving our newsletter, please opt in to be placed on our mailing list. You will receive a maximum of 2-3 newsletters per year and are free to opt out of the mailing list at any time by emailing the research team at [info@spectrum10k.org](mailto:info@spectrum10k.org).

### **5.2 What happens at the end of Spectrum 10K?**

The study results will be presented at research conferences and written up in scientific journals. The individual you are advising for will not be identifiable in any published results.

### **5.3 What if there is a problem?**

If you have a concern about any aspect of this study please contact the research team at [info@spectrum10k.org](mailto:info@spectrum10k.org) who will do their best to answer your questions. In the unlikely event that something goes wrong and the individual you are advising for is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the NHS but you may have to pay your legal costs. The normal National Health Service complaints mechanisms (PALS) will still be available to you (if appropriate).

## **6. Contact Spectrum 10K**

If you have any concerns or need further details before deciding to take on the role of consultee, please contact our research team at [info@spectrum10k.org](mailto:info@spectrum10k.org). If you wish to register the individual under your care, please continue their online registration at [www.spectrum10K.org](http://www.spectrum10K.org). If you do not wish to register them, then you do not have to do anything.

**If you wish to make a complaint about the study please contact your local NHS Trust.**