

INFORMATION LEAFLET FOR CONSULTEE (ENGLAND & WALES) TO BE USED FOR PARTICIPANTS OVER 16 WHO LACK CAPACITY TO CONSENT

We feel your relative/friend is unable to decide for himself/herself whether to participate in this research. To help decide if he/she would like to join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information sheet. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn. If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility. The following information sheet is the same as would have been provided to participants over 16 who have capacity to consent who are being recruited to the IMAGINE study.

INFORMATION LEAFLET FOR ADULTS Please read the information provided

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Please feel free to contact us if there is anything that is not clear or if you would like more information. Take as much time as you need to decide whether or not you wish to take part.

What is the purpose of the IMAGINE ID Study?

Many parents are concerned that their child has delayed development or is slower to learn than normal. Some of these individuals have genetic tests within the NHS where the test shows a change in the genetic code. This is usually called a copy number variant (CNV) and is either a duplication (where an individual has more of the genetic material than most other people) or a deletion (where they have less than most other people) or is called a sequence variant where the letters of the genetic code have altered.

We know that, in general, individuals with copy number variations (CNVs) or sequence variants can experience learning and/or behavioural problems at home and in school. However, we do not know how similar or

different people are with the same genetic changes and whether behaviour problems in an affected person are predictable due to the genetic change.

As most of the CNVs and sequence variants identified within the NHS are rare we aim to collect lots of information on a large group of people in order to know which features are common to individuals with the same condition and which features reflect the natural individual differences between people.

Why is this important?

Parents who have recently received a diagnosis for their child often want to know what to expect in the future. Collecting together the knowledge about individuals with genetic changes will enable new and better treatments and care to be identified for this group of people and their families.

Why have you been invited to join the IMAGINE ID study?

We are inviting all individuals who have received an abnormal genetic result into the study. We aim to recruit 10,000 families from throughout the UK.

Do I have to take part?

It is up to you to decide whether you wish to join. If you decide not to join, your decision will not affect the healthcare you receive in any way. You will be free to withdraw at any time and without having to give a reason.

What will happen if I take part?

If you agree to take part, we will ask you to sign a consent form. You will be asked to provide your contact details and to complete online assessments about your health, behaviour, degree of learning problems and educational support (educational statement) as well as information about the family and lifestyle. We estimate these assessments will take approximately 1 hour in total but you do not have to do this all in one session as the information will be saved and stored as you go along.

We would also like to interview you in person to improve the information we are collecting. If you would be willing to be seen in person please indicate this on the consent form. We will not be able to interview everyone in person and may have to be selective. Interviews in person will take 4-6 hours in your home with 2 researchers attending and will be audiotaped. Visits may need to happen on more than one occasion to do all the tests, games and tasks we would like you to do. If we visit you we will also ask you if you are willing for the research team to take a sample of blood, saliva or hair roots from you at home but you do not have to do this.

What will happen next?

Once you have completed the assessments we will send you a individual report summarising your strengths and difficulties. You may find it a useful summary if you have assessments for services, work or specialist treatments. We will also send a copy of this report to your extended clinical care team. This data and/or other health records will be held on a research database for use in medical research.

What will happen to my data in the future?

It is possible that the information you have given may be of benefit to future research studies without any

need for further involvement from you. In addition, we may find on the basis of this information that you would be suitable to participate in future research studies. It is perfectly OK if you do not want to take part in any future studies. If you are interested in a separate research study then we will contact you to ask whether you want to take part. We may also invite you to participate in studies to obtain your views on the ethical aspects of research involving genetic information.

What are the possible disadvantages of taking part?

There are some people who may find it difficult or distressing to be contacted or to provide some of the information we ask for. Our research team will be available on the phone to discuss any matters with you and to advise where to get further help if needed. Please do not hesitate to contact us or arrange to see your local GP or health professionals if you have found it distressing being approached to take part in the study.

What are the benefits of joining the IMAGINE ID study?

Joining IMAGINE ID gives you a chance to help learn more about living with rare genetic conditions. Your contribution will help other families to gain better information about their child's development and behaviour.

You will receive a personal summary report of your strengths and difficulties. You may find it a useful summary if you need assessments for services, work or specialist treatments.

Will my taking part in the study be kept confidential?

Yes. We will follow best ethical and legal practice and all information about you will be handled in confidence. Information you give us will be stored in a secure database.

The database linking unique sample study numbers to personal details will only be accessed by authorised members of the IMAGINE ID team. Information we have stored on you will not be used or made available for any purpose other than for research and improvements in health care.

Your name or family name or any other personal identifiers will not be in any report or publication, including information about the IMAGINE ID study or the data gathered, which will be released on the internet, journals or other media. Any research data generated and made available to others for further research will have your personal identity removed. On occasions we may ask you for separate written consent to contribute a personal story for education purposes. Telling a personal story may be of enormous value to other families affected by rare diseases and to increase awareness in society about rare diseases in general. It is up to you to decide how much, if any, additional information you wish to give.

Can I know the results obtained from the study?

As yet the genetic basis of potential learning, behavioural or thought problems in people with different sequence variants is not understood. Therefore, it will not be possible to provide information about any individual's genetic status but we will make available a summary of the research findings to all participants.

What will happen if I want to withdraw from the study?

If you withdraw from the study, we agree not to continue to collect data from you. However, data that has already been collected up to the point of your withdrawal will remain in the study.

Who is funding and responsible for the study?

The IMAGINE ID study is funded by the Medical Research Council and is jointly sponsored by the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust. The study was reviewed by Queen Square London Research Ethics committee.

Further information

If you would like any further information about this study, please do not hesitate to contact our Research Team directly on imagineID@cimr.cam.ac.uk or alternatively telephone 01223 254631.

Department of Medical Genetics
Cambridge Institute for Medical Research
Hills Road
Cambridge CB2 0XY
Mobile: 07711 500477
Web address: www.imagine-ID.org
Twitter: [@ImagineIDstudy](https://twitter.com/ImagineIDstudy) and [@ImagineIDnews](https://twitter.com/ImagineIDnews)
Facebook: facebook.com/imagineid.study

The Study is managed by a collaborative team of clinician scientists from the University of Cambridge, University of Cardiff and University College London.

Prof F Lucy Raymond Consultant Clinical Geneticist flr24@cam.ac.uk

Prof Jeremy Hall Consultant Psychiatrist HallJ10@cardiff.ac.uk

Prof Marianne Van Den Bree Psychological Medicine vandenbreeem@cardiff.ac.uk

Prof David Skuse Consultant Child Psychiatrist d.skuse@ucl.ac.uk

Thank you for your interest in the IMAGINE ID Study

Participant Details Form | Please complete in block capitals

Child's Details

Name of Participant (Name of Child)

Date of Birth

Gender

NHS Number (if known)

DD	/	MM	/	YY		
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Address

Mother / Primary Carer Details

Name

Date of Birth

	DD	/	MM	/	YY
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Address (if different from child's)

Father / Secondary Carer Details

Name

Date of Birth

	DD	/	MM	/	YY
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Address (if different from child's)

Genetic Details

- Please attach a copy of the participating child's genetics report or clinic letter.

Or, if the report is not available

- Please complete as much as you can of the following information:

Where did you receive your child's diagnosis? (Which Genetics Centre or Hospital)

Which consultant did you see?

Genetics Family Number

Array/Karyotype Results

Coordinates

Mutation (if applicable)

Other Details

Where did you hear about IMAGINE ID?

Are you registered with UNIQUE charity? Yes No

Are you registered on DECIPHER? Yes No

If yes, please specify your DECIPHER number:

Is your child currently participating in any other research studies? Yes No

If yes, please specify:

Preferred Mode of Contact: Phone Email

Consultee consent for adults who lack capacity

Statements		Please Initial Boxes
1	I am the consultee of the adult named below, and have the authority to sign this Consent Form.	
2	I confirm that I have read and understand the information about taking part in the IMAGINE ID study.	
3	I have had the time to consider the information, ask questions and have received satisfactory answers to my questions.	
4	In my opinion s/he would agree to join the IMAGINE ID study.	
5	I understand that taking part in the study is voluntary and that s/he is free to withdraw at any time without giving any reason and without his/her medical care or legal rights being affected.	
6	I agree to complete online questionnaires about the participant's health, education, family and mental wellbeing.	
7	If I am the parent of the adult participant I agree to answer questions about myself that will help the research team understand the interviews about my son or daughter.	
8	I understand that the participant's medical notes and health records may be looked at by individuals from the IMAGINE ID study. I give permission for these individuals to have access to the participant's records now and in the future.	
9	I understand that the participant's government statement of additional educational support or education, health and care plan may be looked at by individuals from the IMAGINE ID study. I give permission for these individuals to have access to the participant's records now and in the future.	
10	I understand that the information gathered about the participant can be stored for use in future medical research studies aimed at understanding the causes and management of intellectual disability.	
11	I understand that this research may include the participation of industry and commercial companies and that we will not benefit financially if this research leads to new treatments or medical tests.	

Optional Statements

12.	The participant would like to take part in a face-to-face interview study with me and the adult participant that will be audio-taped for research purposes only.	
13	I agree to have samples of saliva, blood and/or hair roots taken from my child for research purposes only.	
14	I agree to be contacted and invited to participate in additional medical research based on the information already provided on the participant's behalf. I will be provided with full information about these studies, when and if I am contacted. I understand that I am free to decide whether or not to take part in these studies.	
15	I give consent for the research team to feedback the results of any research relating to the cause of the participant's problems to his/her extended clinical care team. I agree that the clinical care team can feedback this information to the participant.	

Contact Details

Please complete in block capitals

Name of Participant (Name of adult who lacks capacity)

Name of Consultee

Telephone

Mobile

Email address

Signature

Date

DD	/	MM	/	YY
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Name of Researcher

Family Identification Number

Signature

Date

DD	/	MM	/	YY
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