

## Information Sheet for Adults

### The Third Infectious Intestinal Disease Study (iid3) in the UK

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#### Introduction to iid3

Have you ever wondered why you occasionally get diarrhoea or suffer from vomiting? Well, that's the kind of thing we spend a lot of time thinking about.

That's why we're pleased to say that your surgery is taking part in iid3, a big national study about the gut health. And we'd love it if you would help us by getting involved - whether you suffer from diarrhoea or vomiting a lot, sometimes or never.

This leaflet tells you about why we are doing the study and what we'll ask you to do if you decide to join in.

#### What is iid3 about?

We will find out how many people have diarrhoea or vomiting during a year. We will ask how many of these people go to their doctor when they have diarrhoea. We will also study what germs are causing the symptoms.

Other names for diarrhoea and vomiting are "infectious intestinal disease", "food poisoning", "gastroenteritis" and "gastric flu".

Although there are some official figures about diarrhoea and vomiting, we want to find out how good they are.

#### What sort of study is iid3?

This is a large survey. If you decide to join in, you'll be one of thousands of people from England, Northern Ireland, Scotland and Wales helping us find out more about diarrhoea and vomiting.

### Who is organising and paying for iid3?

Newcastle University is organising and sponsoring iid3. We also have several other research partners who will be working with us and GPs all over the UK. The research partners are the University of Oxford (leading on the organisation of the research work with GPs and secure storage of research data), Liverpool Clinical Laboratories and the University of Liverpool (leading on clinical microbiology studies and secure sample storage respectively), the UK Health Security Agency and Public Health Wales (leading on specialist microbiology studies), and Public Health Scotland (leading on surveillance studies). As well as organising the whole study, Newcastle University is also leading on the data analysis.

The research is being funded by the Food Standards Agency, the Government body that makes sure our food safe.

### Why have you contacted us, and do we have to take part?

The reason why you're receiving this invitation is that your name has been picked at random by your doctor from their list of patients. We'd like it if your whole household would sign up to the study so that we can investigate the spread of IID in households. We would like to know how many times infection gets spread amongst household members.

However, **it's up to each of you whether you take part or not**. If only some of you are interested that's OK. We will not ask for any data or samples from members of the household who do not wish to take part or do not provide their consent.

And if you all decide you'd rather not take part, rest assured that your healthcare will not be affected in any way.

## What happens next if we agree to take part in iid3?

For those of you who agree to take part, your GP practice will set you up as a study participant and arrange for you to get regular study updates. All you have to do is:

1. Each fill in a consent form. This lets us know that you are happy to take part in iid3. Your GP practice will record consent in your medical record.
2. Each fill in a short questionnaire which will help us to understand a bit more about your household. If any of you send us back the questionnaire but forget to include the consent form, we will assume that you are happy to take part. Your GP practice will record your implied consent in your medical record.
3. Tell your GP Practice as soon as possible if any of you are ill with diarrhoea or vomiting. In case you forget, the Practice will contact you every week for one year to find out if you've been ill with diarrhoea or vomiting. All we need is a simple yes or no. You can let them know them in advance how you would prefer to be contacted e.g. email, text or other method to suit you, such as through the Patient Access App.
4. Contact your GP Practice as soon as any of you become ill, and they will send you a faeces (poo) sample pot to test for germs. Then please fill in a symptom questionnaire about your illness. If any of you have forgotten to send us a consent form, or initially declined to take part, but you send us a sample anyway, we will assume that we can test the sample that you have provided. We will send the results to your GP. We will then destroy the sample straightaway after we have tested it.

## What will happen to the faeces (poo) sample?

The sample will be sent to an NHS clinical laboratory in Liverpool where they will use the most modern tests available to look for over 20 germs (which is a lot more germs than samples are usually tested for). The laboratory in Liverpool will need to know who you are (your name, date of birth, address) so that they can perform the tests and send the results back to your GP. This is normal practice, and they will keep the information confidential. If they find any germs, the germs will be sent to a reference laboratory (in London or Swansea depending on the germ) where they will undergo further testing, like

DNA fingerprinting, and those results will also be sent back to your GP. No-one will test your DNA.

If the laboratory in Liverpool finds a germ of public health significance, like *Salmonella* or *E. coli* O157, they will have to tell the local Health Protection Team because they are required to do so by law. Someone from the Health Protection Team may then contact you, as is the routine if your GP practice or local hospital find a food poisoning germ.

Positive results from all laboratory tests are also reported, by law, to UK national surveillance centres but these are sent, and kept, in confidence.

Finally, if you agree, we'll store the sample for a minimum of 5 years after the end of the study in the Liverpool University Biobank (LUB) so that it can be used in future research (for example to look for new causes of diarrhoea). If you agree to your sample being stored for future research, your consent form may be shared with the researchers at the LUB who are responsible for sample storage. They need to know about the consent form to fulfil their legal obligations under the Human Tissue Act. The sample will be given a unique code before it is stored in the LUB so that it can never be linked back to you. You may withdraw your consent to have your sample stored and used for future research at any time by contacting [biobanking@liverpool.ac.uk](mailto:biobanking@liverpool.ac.uk) quoting the IID3 Study.

### How will we use information about you?

We will need to use information from you, from your medical records and your GP for this research project.

This information will include your :-

1. NHS number
2. Full name
3. Contact details
4. Ethnic group
5. History of bowel problems
6. Symptoms of IID
7. History of foreign travel
8. Results of the stool sample tests

We'll also ask about the job of the main earner in the household so that we can make sure that the study covers the whole of society. We will link your

information with other members of your household, but only if we have their consent, so we can track any spread of IID in households.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. We will not share any data with the Food Standards Agency that could identify you.

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 you took part in the study.

### **What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.

We need to manage your records in specific ways 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 you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. With your permission your sample would be stored securely for a minimum of five years in the Liverpool University Biobank. If you forget to send back the consent form we will not store your sample.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information  
 at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)  
 our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)  
 by asking one of the research team  
 by sending an email to [data.protection@newcastle.ac.uk](mailto:data.protection@newcastle.ac.uk)

### **What are the benefits in taking part in this Study?**

You'll be helping the Food Standards Agency decide whether current food safety measures have worked or if they need to make changes to safety policy. So, it's an important study that could benefit everyone in the UK.

### **Are there any risks in taking part in this Study?**

We do not think that there are any risks in taking part in this study.

### **After the Study starts, can I change my mind?**

You can leave the study whenever you want. The information you have given up to that point will still be helpful to us.

### **What if I have a question or there is a problem?**

If you are not sure about any aspect of this study, you should speak to your GP practice where they will try to answer your questions.

If you are unhappy and wish to complain you can do this through the NHS Complaints Procedure ([england.contactus@nhs.net](mailto:england.contactus@nhs.net)) stating 'For the attention of the complaints team' in the subject line. Alternatively you can contact the Research Integrity and Governance Manager at Newcastle University ([res.policy@ncl.ac.uk](mailto:res.policy@ncl.ac.uk)).

### **What happens when the Study finishes?**

You will be involved in the study for one year. The results will be published as a report, in medical journals and presented at conferences. Your name and information that can identify you will not be used. If you would like us to send you a summary of the results, please initial the box on the consent form. The summary will be available from the end of 2026.

We will ask your permission to contact you in the future to find out if you are interested in taking part in related research.

### **Who has checked the Study?**

Before a study like this can go ahead it undergoes strict checks by an NHS Ethics Committee. This Study has been checked by the East Midlands – Nottingham Research Ethics Committee.

### Contact Details

During office hours: [sponsorship@newcastle.ac.uk](mailto:sponsorship@newcastle.ac.uk)

Out of office hours: [sponsorship@newcastle.ac.uk](mailto:sponsorship@newcastle.ac.uk)

Complaints: [sponsorship@newcastle.ac.uk](mailto:sponsorship@newcastle.ac.uk)

**If you decide to take part in the Study, you can keep this information sheet and a signed copy of the consent form.**

**Finally, we would like to thank you for taking the time to read this information sheet.**