

Taking part in research

This leaflet contains four sections:

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Summary

Research is important to improve the lives of people experiencing mental health conditions and dementia. Taking part in research can make a real difference to future treatments and care. However, many people are unaware that it might be an option for them to participate as part of their care and treatment.

We want to offer everyone who uses our services the opportunity to learn about and take part in research. For this we are creating a database of people interested in being contacted about research.

This leaflet explains how you can be contacted about taking part in research, now or in the future, and how you can express your preferences. Whatever you decide now, there's no commitment to take part in any actual research studies – all we'd like to know now is whether you're interested in being contacted about research that may be relevant to you.

From time to time, a member of your care-giving team may give you information about studies that may be relevant to you. Full information will always be provided and you are free to say no at any point. You may also choose to receive information about relevant studies directly from our researchers. All researchers work for or are approved by Cambridgeshire and Peterborough NHS Foundation Trust (CPFT). If you are happy for our researchers to contact you directly, you will need to give your consent for them to review your CPFT medical records. This can help them find out if you might be suitable for a specific research study and contact you directly. Information that can identify you will not be given unless you've said that it is OK. If you are suitable for a particular project, the researchers will contact you and discuss the project in more detail with you. You are then free to agree to take part or not, without giving any reason.

Your decisions about taking part in research will never affect the standard of care you receive. You can also withdraw your consent at any time without giving a reason.

You can tell us if you are happy to be contacted with information about particular studies by choosing a colour:



Red means “no”. Your identifying details will **not** be given to our researchers, and they won't see your full identifiable medical records.



Yellow means “maybe”. Your health care professional might ask you about research projects. Each time, they'd ask you whether you want information about that project, and whether you'd allow those researchers to see your full records. [Choosing yellow doesn't mean that you have to take part in any future project.](#) **Until you've chosen, we'll assume yellow.**



Green means “yes”. It means that you allow our researchers to see your full records, to see if you might be suitable for a research project. It means that you allow them to write to you, to tell you about the project and invite you to take part. [Choosing green simply allows our researchers to write to you — you don't have to take part in any future project.](#)

Please choose a colour by filling in the decision form called “*Would you like to be contacted about research?*”. If you don't have a copy, see www.cpft.nhs.uk/research and click on “Research Database”.

CPFT also uses anonymised medical records for research, sometimes after linking it to other national data sources. This leaflet explains how, and how you can opt out if you want.

Would you like to take part in research?

This leaflet explains how Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) uses health data for research, and how you can take part if you want to, or opt out completely if you wish.

Research helps us understand more about mental health related conditions and dementia, the treatments we use, the care we deliver, and the advice we offer. Our aim is to convert research findings into clear improvements in treatments and services.

Volunteers who take part in research play a crucial role in improving the lives of thousands of people.

You could help by taking part in research that's relevant to you. This might be to do with symptoms that you have now, or that you've had in the past, or even symptoms that you've never had (for comparison to other people who have). All these things can help research. We'd be grateful for any help you can give.

We are creating a database of people who are interested in being contacted about research. We'd like to know whether you're interested. Whatever you decide now, there's no commitment to take part in any actual research studies — all we'd like to know now is whether you're interested in being contacted about research that may be relevant to you.

Your decisions about taking part in research will never affect the standard of care you receive.

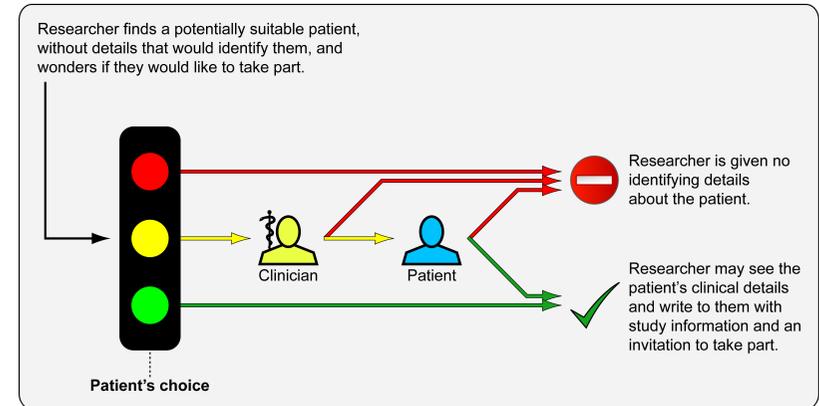
Do you want to choose RED, YELLOW, or GREEN?

If our researchers want to ask you about taking part in research, whether they're allowed to do so (and even whether they're allowed to know who you are) depends on whether you choose the RED, YELLOW, or GREEN option. Here's what they mean:

-  **RED.** This means that your identifying details will not be given to our researchers, and they won't see your full identifiable medical records.
-  **YELLOW.** This means that all requests from our researchers are sent to your clinician. Your clinician would usually write to you about each request. No information will be passed to the researchers unless you agree. If you are interested in a particular study, you'd be asked to allow those researchers access to your CPFT records to check if you are suitable, and your details would be passed to the researchers so they can write to you. [Choosing this option doesn't commit you to taking part in any future project.](#)
Until you've chosen, we'll assume YELLOW.
-  **GREEN.** This means you agree that our approved researchers may have access to your CPFT records to see if you might be suitable for a project, and may write to you directly about any projects that you are potentially suitable for, giving you details of their research and inviting you to take part. [Choosing this option simply allows our researchers to write to you — there's no commitment to take part in any future project.](#)

We hope very much you'll choose one of these options, particularly GREEN, because we believe research makes a difference.

The picture below summarizes the process.



What else should I know before I choose a colour?

It is possible that you may not be contacted at all, and it is possible that you will be contacted about a study which is not directly relevant to the symptoms you have been experiencing. There may not be a project suitable for you to take part in straight away, but we will keep people who choose *green* or *yellow* updated about our research through an annual newsletter.

What if I change my mind?

You can change your mind at any time. Simply speak to your care coordinator or contact the Research Database Manager (whose details are at the end of this leaflet).

If I'm contacted about research, what should I know?

Your decisions about taking part in research will never affect the standard of care you receive.

Taking part in research is always voluntary. **You are always free to say yes or no.** You never have to give a reason for your decision.

If a researcher contacts you, they would give you full information about their project before asking you whether you'd like to take part. Before anyone can take part in research, they must be fully informed about what the study involves (including any discomfort or risk that it might involve, if there is any possibility of this) and must have given their consent.

If you do take part in a study, you may withdraw your consent at any time, and stop.

The researchers will ask you questions to make sure that you are suited to the study and that it is safe for you to take part.

If you have questions about the research study, feel free to ask the researchers anything you want.

Is my information held securely?

Your information is held securely at all times. We comply with the Data Protection Act and all other relevant laws. Information that can identify you will never be given to researchers outside your care-giving team without your permission (except if required by law). Our researchers work under strict confidentiality guidelines. Your information will only be used for medical research purposes. Information about you will never be disclosed to any other party.

How do I know that research supported by CPFT is ethical and proper?

Every research study in the UK involving people must be approved by an independent Research Ethics Committee, which ensures that the research is legal and ethical. CPFT's research database and its methods have also been approved by an NHS Research Ethics Committee. In addition, all studies carried out at our Trust are reviewed by CPFT to ensure that they are conducted in the safest and most ethical way possible.

Research at CPFT

This section explains more about health data, research at CPFT, and how your health data can be used for research.

What is health data?

Health data is all the information recorded about you by anyone looking after your health. It covers health (such as a diagnosis of depression, or a record of medication or therapy) but also **contains** other personal data (such as your address and other personal information that you told us).

What's meant by "clinician" and "researcher"?

By "clinicians" we mean any health care professionals in our NHS Trust who are looking after you, such as your care coordinator, psychiatrists (doctors), psychologists, nurses, pharmacists, therapists, and others. They have access to your health data held by CPFT.

By "researchers" we mean people who conduct research approved by CPFT. Some of our researchers are also clinicians, and some are non-clinicians. Some work in our Trust, some work in our partner organizations such as the University of Cambridge, and some do both.

What sort of health research does CPFT do?

CPFT conducts research and works with partner research organizations, such as the University of Cambridge. Research from these organizations into brain function and mental health problems is some of the best in the world.

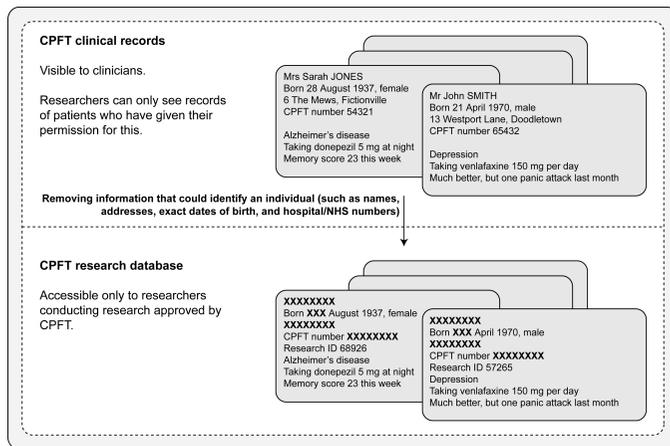
There are different types of health research that use people's information:

- **Population-based studies** look at the records of large numbers of people to see if there are any links between things like diet, or family history, and particular illnesses. They help answer questions about what causes illness and how to treat and prevent it.
- **Basic research studies** are research projects that may involve people. They look at the causes and mechanisms of complex illnesses, such as depression and schizophrenia, aiming to improve our understanding of the diseases, and to lead to improvements in diagnosis and treatment. Some studies of this kind may involve questionnaires, interviews, computer games, puzzles, brain scans, or completing a diary.
- **Clinical trials** are research projects involving people. They test whether treatments are safe and how well they work. They may test new therapies or medicines, combinations of existing treatments, or whether giving a treatment in a different way makes it more effective or reduces side effects. Some trials are designed to find better ways to prevent or diagnose disease or to deliver health services.

Information on our current studies is at www.cpft.nhs.uk/research.

How is my health data used in health research at CPFT?

Your clinician may ask you if you are interested in taking part in research. CPFT also has a research database, derived from clinical records, but with identifying information (such as names and addresses) removed. Our researchers can use the research database in different ways, depending on the type of project.



Population-based studies

For a population-based study using information that can't be tracked back to you, consent is not necessary. If information obtained from your data is used, the researchers won't know who you are, so you will not be approached for your permission. The researchers will analyse the data and publish their findings.

If you wish, you can opt out from the use of your data even after all the details that could identify you have been removed. To opt out, simply tell us on the decision form.

Data linkage studies

CPFT's Clinical Data Linkage Service links information from CPFT clinical records to a number of other information sources outside CPFT – for example, national NHS information such as summaries of Accident and Emergency visits. This helps certain important types of research: in particular, studies using anonymised data to answer questions not possible with CPFT data alone. Linked information is restricted even more tightly. Sometimes, names, NHS numbers, and other identifiers are used to link data, but they are deleted before researchers are given access to any data. Where identifiers are used temporarily, special permissions are required, and CPFT applies the NHS National Data Opt-Out (www.nhs.uk/your-nhs-data-matters) as well as CPFT's own opt-out. Researchers never see anyone's identity, and CPFT never allows researchers to contact you based on linked information. For details of the data sources that CPFT links to, and how, see www.cpft.nhs.uk/research → "Research Database". For details on how to opt out, see the end of this leaflet.

Studies involving patients (basic research and clinical trials)

Our researchers can look for patients who might fit their study's requirements. For example, they might be looking for adults with depression who've had a particular kind of antidepressant medication. Their search of the database might find 600 people like this. The researchers don't know who they are (since there are no identifying details) and don't know if they're interested in taking part, but would like to ask. What happens if you are one of these people?

- For some studies, the researchers might prefer to contact you directly. **You may choose what happens in this circumstance, by choosing red or yellow or green** (explained earlier in this leaflet).

- Some studies would need your clinician's involvement. For these studies, yellow is used in place of green. Everything else works the same as before.

If I have further questions, who should I ask?

Do you have questions about a specific research study?

- For questions about a specific study, it's usually best to ask the researchers.

Do you want to know more about CPFT's research in general?

- More information is on our web site, www.cpft.nhs.uk/research.

Do you want to change your red/green/yellow preference?

- You can complete the decision form and give it to your care coordinator or send it to the CPFT Research Database Manager. If you have questions, ask your care coordinator.
- You can also contact the CPFT Research Database Manager. The address is [FREEPOST CPFT RESEARCH DATABASE MANAGER](mailto:research.database@cpft.nhs.uk). The e-mail address is research.database@cpft.nhs.uk. You can also phone 01223 219400 and ask for the Research Database Manager.

Do you want to opt out from the use of your data even after all the details that could identify you have been removed?

- You can complete the decision form, tell your care coordinator, or contact the Research Database Manager (the details are above).

Do you want more details about how your information is used and kept safe?

- For information on how we look after your personal information, please see CPFT's leaflet "Taking care of your information".
- For information on how medical records are used in health research across the UK, please see the leaflet "Your health records save lives" by the NHS National Institute for Health Research at www.nihr.ac.uk/publications.

Do you want to complain?

- We want your experience at CPFT to be positive. If you are not happy about something at CPFT, we will try to help you. Please contact the Patient Advice and Liaison Service (PALS) on Freephone 0800 376 0775. If you decide you want to make a complaint, we can advise you how to do this.

For all other questions, feel free to ask your care coordinator.

If you would like a large print, audio, Braille or a translated version of this leaflet then please ask us.

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