



University Hospital **NHS**
of South Manchester
NHS Foundation Trust



UHSM

MANCHESTER ADULT
CYSTIC FIBROSIS CENTRE

How to get involved in **Cystic Fibrosis Research**



Information for patients
and the public

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GENERAL INFORMATION

WHO IS THIS BOOKLET FOR?

- People with cystic fibrosis (CF)
- Families and carers
- Members of the public

WHAT IS RESEARCH?

Research is a step by step process that involves collecting and examining information in order to improve our knowledge and understanding.

Research may be carried out as a **clinical trial**, for instance of a new treatment or treatment approach. It could also be **observational research** study which involves collecting and analysing information about patients.

WHAT IS A CLINICAL TRIAL?

A **clinical trial** is a carefully designed research study looking at the effects of a drug or medical treatment on a group of patients. The trial may be of a new drug, or a new way of giving a drug that has been used before. It will often involve some patients receiving active treatment, and some receiving a harmless substitute called a placebo. Usually neither the patients nor the researchers are told who is receiving which treatment. This is in order to prevent our expectations influencing the results in any way (this is called a double-blind trial).

Clinical trials help to develop and improve treatments, increase knowledge about illnesses or conditions and may answer questions about how well a drug works. They can involve anything from a few volunteers to thousands and may be conducted in a local region or across the world.



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Do all studies involve taking medicine?

No. Here at the Manchester Adult CF Centre we carry out other types of study which have varying levels of involvement on your part.

Some studies, known as **observational studies** are when the researcher observes a group of people with CF in order to establish patterns in their health. For example an observational study to determine how acquiring *Pseudomonas* infection affects people.



These types of studies are just as important as clinical trials involving medicines. They help us understand more about CF which in turn helps us to select possible treatments. Although you are not required to take medicine you will be monitored by the research team and may be required to have some tests carried out as in a clinical trial (for example, a blood or sputum sample or an exercise test). The type of test will depend on what the study is wanting to measure. These studies go through the same strict review process as clinical trials.

Why is getting involved in CF research important?

Research is the only dependable way to build on what we know and improve the treatments we can provide to people with CF. Participating in research assists advances in science which could lead to new discoveries and more effective treatments. By participating you are assisting a vital process that advances scientific knowledge.

Research has given us a better understanding of CF and helps us to develop and test treatments to see what the best treatment out there for you is. It is because of this improved care that life expectancy has improved so much (in 1964 life expectancy in CF was just 5 years), and with our continued commitment to research this will continue to get better.



What has research ever done for me?

Every important advance that has been made in medicine is based on evidence and data gathered from clinical research trials.

The medications that you take, for example antibiotics such as colomycin and tobramycin and other therapies including DNase and hypertonic saline, were all developed, tested and approved through research.

The benefit of these medications had to be established in clinical trials before they could be made available to you. Research has provided you with treatments that help you and your doctor manage your condition in the best way possible.

All doctors and clinicians are obliged to base their decisions about the best care for their patients on their experience and recent evidence.



RESEARCH AT MACFC

At Manchester Adult CF Centre we have a very active research programme which is central to our ability to deliver cutting-edge care to our patients. We are keen to give our patients as many opportunities to take part as possible and hope that you will also be enthusiastic about this programme.

Why get involved in a research study?

There are many different reasons for getting involved in a research study:

- Some people want to become more active in their health care and feel good about helping advance medical knowledge.
- Some people feel that they benefit as they get regular follow up meetings when involved in a clinical study. This can mean that health problems may be found earlier.
- Research studies also offer high quality care and patients may be among the first to benefit if a new treatment is proven to work.
- Becoming involved in a clinical trial gives patients an active role in a decision that affects their treatment and their life.
- Patients also have the chance to help others and improve treatment.



How could I get involved in research at MACFC?

Many members of our clinical team are involved in research. For all research studies there is a list of criteria that people who are interested in taking part must meet first. A doctor or member of the clinical team responsible for the named study will look at a list of patients due to attend the clinic. They will look at your medical records and compare your details (for example; your age, medications and lung function) with their criteria. If your details match they will come and talk to you. This may be at a clinic appointment, while you are an in-patient or they may even telephone you or post information out to you.

Sometimes studies are advertised on posters or leaflets around the unit, with details of how to get involved. We also work closely with the **Medicines Evaluation Unit** (see overleaf). If you are approached to take part in research you will be given a detailed information sheet about the study and given time to decide whether or not to take part.

Patient Forum

We are keen to establish a forum where patients can talk about research, and where doctors and researchers can get patients' opinions. We may need opinions on what patients view as priorities for research in general, or on a specific proposal we have put together. Or we may need help looking through a patient information sheet to make sure that it is easy to understand.

If you think you would like to help with any of these activities then details of how to get in touch, and what research opportunities we have at present, can be found on our website, or you can email us directly:

visit : www.uhsm.nhs.uk/cysticfibrosis

email : research.macfc@uhsm.nhs.uk





MEDICINES EVALUATION UNIT

We are very fortunate at MACFC that the [Medicines Evaluation Unit \(MEU\)](#), a state-of-the-art clinical trials facility, is located just opposite the CF centre.

The [MEU](#) work closely with drug companies in helping to develop new therapies for a range of lung conditions, including CF. All studies at [MEU](#) go through the same detailed review process as other studies and are conducted with the involvement of consultants from MACFC.

If you register with the [MEU](#) they will also contact you if there are clinical trials that they think you may be interested in. Registering your interest does not sign you up to taking part, just to being informed about opportunities when they arise.

For more information and details on how to register with [MEU](#), please visit:

www.rewardingresearch.co.uk or call [0800 655 6553](tel:08006556553)

Is taking part in research studies voluntary?

If you are approached about a study you should take time to discuss it with your family, friends and GP if you so wish.

You will be provided with an information sheet that will have the contact details of the lead researcher if you need further information or advice at this stage. If you are happy to take part you will be asked to sign a consent form.

There is no obligation to take part in any study. Our staff will not put you under pressure and you will receive the best care possible whether you take part in a study or not.

If you do decide to take part you can withdraw at any time without giving a reason and this will not affect your treatment either now or in the future.

How can I find out about the results of research?

Generally, people participating in major research studies will be informed about the results personally. All research participants are very welcome to contact the research team and request any information that may interest them.

Results are often published worldwide in scientific journals and presented at international conferences. You can also contact us directly by:

email : research.macfc@uhsm.nhs.uk



SOME QUESTIONS YOU MIGHT WANT TO ASK BEFORE DECIDING TO TAKE PART IN A STUDY

- What is the point of this study?
- Why have I been chosen?
- What will I have to do if I agree?
- Are there any risks?
- How long is the study expected to last?
- How long will it be before the results of the study are known?
- Will you tell me the results?
- What extra tests or appointments will I have?
- Will I need to take time off work?
- Will travel expenses be paid?
- How can costs be reclaimed?



How will I know that the study is properly designed and safe and will be properly managed?

All research staff train in '**Good Clinical Practice**' which is an international standard which ensures that a study is of good scientific quality and the rights, safety and well being of patients are protected.

There are strict rules for clinical trials and your safety is very important. Before a study starts, the person doing the research has to think carefully about what they are aiming to achieve and how they are going to achieve it. They develop a clear plan of how the research will be carried out.

Once they have decided this, all research studies at MACFC and the MEU have to go through an extremely strict and detailed review process by an independent **Research Ethics Committee** whose main interest is looking after your safety.

The Research Ethics Committee will check that the study is worthwhile, well organised and above all safe, with all potential risks and discomforts minimised.

Participants in research studies are informed of all known risks and potential benefits. You will not be asked to stop any effective medications that you are already taking.

GLOSSARY OF RESEARCH TERMS

Controlled: In this type of study, the new treatment is compared with a treatment that is already in use, or an inactive treatment (placebo). You may be assigned to the experimental group (new treatment) or the control group (usual or inactive treatment).

Single-blind: A blinded study is one in which you are not told which treatment you are being given so that you are not influenced by your expectations of the effects of treatment.

Double-blind: This is similar to a single blind study, but the researcher also does not know which group you are in. Your doctors can find out which treatment you have been receiving if they need to.

Placebo: In some studies a treatment is compared against a harmless inactive treatment known as a 'placebo'. This is done so that everything is the same for both groups except for the experimental treatment. The experimental group may get a tablet containing a new medicine and the control group will get a tablet that looks the same but is made of sugar.

Randomisation: The treatment you are given as part of a randomised research study is decided by chance (like the flip of a coin). Random assignment makes sure that the people have an equal chance of being part of the study group.

Informed consent: The process in which you learn the key facts about a clinical trial or research study and then agree voluntarily to take part or decide against it. The process includes signing a form that describes the benefits and risks that may occur if you decide to take part.



FURTHER INFORMATION

For further information on cystic fibrosis research, please take a look at the following useful websites:

Cystic Fibrosis Trust (www.cftrust.org.uk)

A national charity in the UK which funds research into the disease and provides information and support for patients and families.

Wythenshawe Hospital (www.uhsm.nhs.uk)

Wythenshawe Hospital is large teaching hospital providing services for adults and children in several fields of expertise including cardiology, heart and lung transplantation, respiratory conditions, burns and plastics, cancer and breast care services. The hospital is recognised in the region and nationally for the quality of its teaching and research.

UK Clinical Trials Gateway (www.ukctg.nihr.ac.uk)

The UK Clinical Trials Gateway provides easy to understand information about clinical research trials running in the UK, and gives you and others access to a large range of information about these trials.

Medicines Evaluation Unit (www.rewardingresearch.co.uk)

The MEU specialises in performing clinical trials in respiratory, inflammatory medicine and related areas. The MEU has a reputation for performing high quality clinical research.





We would like to take this opportunity to thank the Belfast Health and Social Care Trust Children and Adult Cystic Fibrosis Team for sharing their patient booklet with us which has facilitated the production of this leaflet. We are also very grateful to the patients who kindly reviewed this leaflet.

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