



**Study Title: Affective Disorders Research Database
Participant Information Sheet (Version 1.2, updated: 14.03.17)**

Invitation to participate in the database

The Affective Disorders Pathway is inviting patients to take part in research. We are running a pilot scheme to find patients who are happy to take part in research run by the Trust. Please take your time to read through this information sheet and do ask if you have any questions or require further information.

What is the purpose of the database? Will my data be confidential?

We have created a research database for patients who are interested in research studies within the Affective Disorders Pathway (this means anyone experiencing mood or anxiety difficulties). This is an 'opt-in' service and it is not expected that everyone will wish to take part. If you are interested in being contacted about research studies, you will be invited to an assessment with a trained Assistant Psychologist. The assessment involves a structured clinical interview and some questionnaires. A copy of this information will be kept in your clinical records. We are unlikely to find any information that you are not already aware of, but we will discuss this with you if this does occur. We will also inform members of your care team and record this in your clinical records.

If you disclose that yourself or anyone else may be at risk of harm, the researcher is legally obliged to inform your clinical care team.

In the research database, we will also store the information from the assessments, your NHS number, initials and date of birth. We will then be able to match up possible research studies that might suit you. We also ask for your permission to share this information and information stored in your electronic clinical records with NHS approved researchers so that they might be able to contact you directly if their research studies are a suitable match for you. We might also use an anonymised version of this information for audit studies or feasibility for potential research studies.

You will only be contacted by a researcher if there is a research study that may suit you. It is possible that the Trust may not be completing any studies suitable for you, thus you may not be contacted.

What is involved if I agree?

If you decide to be included, then we will collect the following information: your initials, date of birth, your preferred contact details, along with information regarding your current clinical issues from the interview and from the questionnaires. The assessment itself would take between 1.5- 2 hours in total, which could be done at the same time as a routine clinical appointment or separately depending on your preference. Unfortunately we cannot pay travel expenses for you to attend the assessment. If you do go on to take part in a research study, some studies offer a small amount of compensation.

The assessment includes:

- A Structured Clinical Interview about your mental health
- The Work and Social Adjustment Scale; to assess how you are getting on day to day
- The Warwick Edinburgh Mental Health Well Being Scale; to assess your general mental health and wellbeing

Some people may also be asked to complete:

- The Hamilton Rating Scale for Depression;
- The Yale- Brown Obsessive Compulsive Scale; to assess obsessive compulsive symptoms
- The Penn State Worry Questionnaire; to assess anxiety
- The Revised Impact of Event Scale; to assess posttraumatic stress
- The Panic Disorder Severity Scale- self report version; to assess panic

Why can't you just use my clinical records?

From the assessments, we will gather specific information to find which research studies are best for you. This specific information isn't always available in clinical records (e.g., a score on a depression rating scale) and we would like your permission for researchers to access this information.

We ask your permission to allow researchers to access your clinical records in addition to the research database. This is to ensure they have the correct contact information if you might be suitable for a study, and further check suitability.

Who can access the database?

Researchers will only be allowed to access this information if they specifically state this in their ethical approval forms for their studies and apply to the Research Database Management Committee for approval. Researchers requesting access to the database would need to be part of Cambridgeshire and Peterborough NHS Foundation Trust and would need an NHS contract or honorary contract. Researchers who are permitted to use the database will be have access to participants' contact details, diagnosis and clinical records relating to their care from the Affective Disorders pathway. The research team managing the database will also be able to access, edit and monitor use of the database.

Only studies that are ethically approved are allowed to recruit in the Trust. This is a pilot project so the research database will be sustained for 12 months. After this, we will review the progress of the database. In line with NHS restrictions, we will hold the data for an additional 15 years after it is collected, for the storing of data.

What if I don't want my information to be included on the database? Are my rights affected?

Your rights will not be affected. If you decide to opt-in to the research database, taking part in research studies may or may not help with your clinical care. However, a decision not to take part does not change your usual standard of care.

What happens if I wish to withdraw from the research database?

You can withdraw your information from the research database at any time and without giving any reasons. This will not affect the usual standard of care you receive from the team. We will remove your details from the research database immediately; however, we will not be able to remove the information from your clinical records. After you are discharged, we will ask you if you would like to remain part of the research database and this again is your choice. You also have the option to allow your details to remain on the database but not allow any researchers to contact you anymore, at any point.

What if I become unwell whilst on the database?

Sometimes people who become unwell with mental health problems lose capacity to legally give consent. This means that they become too poorly to make decisions, such as whether you would like to take part in a research study. We will ask your care team or GP to let us know if this happens to you, just so that no researchers contact you when you are not well enough to make decisions. If you would like to take part again when you get better, we will go through the consent process again.

What happens now?

If you would like to take part, we will invite you for the assessment. If you do not wish to take part, that is fine. It is entirely your decision. Please remember that even if you are interested in being involved in the database, there is no commitment to take part in any research studies.

To participate please contact:

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