



PARTICIPANT INFORMATION LEAFLET

Title	BioDepTT: Biobank for Depression, Tallaght University Hospital and Trinity College Dublin
Research Site(s)	<ul style="list-style-type: none"> • Tallaght University Hospital • Trinity College Institute of Neuroscience • Dublin South Central Mental Health Service
Principal Investigator(s)	<p>John R. Kelly, Consultant Psychiatrist and Associate Professor in Psychiatry, Trinity College Dublin (TCD), Trinity Centre for Health Sciences, Tallaght University Hospital (TUH), D24 NROA, kellyj37@tcd.ie, (01) 463 5200</p> <p>Andrew Harkin, Professor in Pharmacology, Pharmacy, Deputy Director of Trinity College Institute of Neuroscience, TCD</p>
Co-Investigator(s)	<p>Claire Gillan, Professor in Psychology, Trinity College Institute of Neuroscience, TCD</p> <p>Martha Finnegan, Consultant, Psychiatry of Later Life TUH Clinical Senior Lecturer TCD</p>
Data Controllers (joint)	Trinity College Dublin and Tallaght University Hospital
Data Protection Officer	Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2. dataprotection@tcd.ie
Data Controller (medical records)	Tallaght University Hospital and the HSE
Data Protection Officer (TUH)	Data Protection Officer, Tallaght University Hospital, D24 NRO, DPO@tuh.ie

Invitation to take part in a biobank

You are being invited to take part in a research biobank to be carried out at Tallaght University Hospital (TUH) and the Trinity College Institute of Neuroscience (TCIN) by Dr John R. Kelly and Professor Andrew Harkin.

Before deciding whether to participate or not, you should understand the purpose of the biobank and what your participation will mean for you. To enable you to make an informed decision please take the time to read this participant information leaflet (PIL) carefully and discuss with others, if necessary.

If there is anything that is not clear or if you would like more information, please ask Dr John R. Kelly or a member of the research team. You should read the information provided in this leaflet carefully. Take time to ask questions – do not feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this biobank so that you can make a decision that is right for you. You may wish to discuss it with your family, friends or GP. The process of providing this information to help you decide whether to participate is called the “Informed Consent Process.”

There is a ‘Key Words’ section at the end of this document that explains some of the terms used in this leaflet.

PART 1 – THE BIOBANK

What is the purpose of this biobank?

Health research takes many years and needs large numbers of people to donate their samples and healthcare data. Biobanks can speed up research by having samples and associated healthcare data ready to use when researchers need them.

This Biobank will collect biological samples and associated healthcare data to be used by approved researchers, to better understand and learn more about Depression.

Researchers may investigate different aspects of Depression and related conditions in order to develop better prevention, diagnosis, and treatments. This includes the causes of Depression, how other health conditions affect Depression, how Depression progresses over time and its long-term impact.

Why am I being asked to take part?

You are being asked to take part because you have either depression or are a healthy person who can be a “control” for (someone to compare with) a person who has depression.

Do I have to take part?

No. You do not have to take part. Your decision is completely voluntary and will not affect your medical care now or in the future. Consenting to both the biobanking and the associated specific study; “**the investigation of the anti-inflammatory effects of psychedelic compounds on blood cells in Depression (Immuno-Psych)**” is not required. You can consent to one part while declining consent for the other.

What if I change my mind?

You can change your mind at any time. Please contact Dr John R. Kelly if you have changed your mind.

At that point, if you wish, the team will destroy any of your remaining samples and associated data. However, it will not be possible to destroy samples already being used in research projects or to remove your data from research that has already been completed or is ongoing

as this could impact on the research results. We will keep a record of the destruction of your samples and any associated data that had been stored if you withdraw.

What will happen to me if I agree to take part?

If you decide to take part, a member of the research team will discuss this information leaflet and consent form with you. It should take about half an hour to take you through the consent process and answer any questions you may have. You will be given a copy of your signed consent forms and this leaflet to keep.

If you agree, any residual blood samples which you donated for the research study – **“the investigation of the anti-inflammatory effects of psychedelic compounds on blood cells in depression”** will be stored indefinitely in this biobank. We may also ask you to provide follow-up samples at a later time, but you can always say no. We will also access your medical records.

Will genetic (genomic) research be carried out on my samples?

Yes, we will extract DNA from your blood to carry out research on Depression. Your genome is the total of all of your DNA and contains all the information to run your body. It is unique to you, and you inherited it from your parents. Today, it is possible to read each of the 3 billion letters that make up the code of your DNA, using a technology called sequencing.

Researchers may use sequencing to determine the letters in your DNA, RNA, or proteins (see Key Words) to understand if differences in your genome might make you more likely to suffer from Depression. As these analyses are carried out for research, and not a clinically validated diagnostic test, we are not able to return any individual results to you.

Are there any benefits to me or others if I take part in the biobank?

Research can lead to better diagnostic tests, treatments and a better quality of life for people affected by Depression. The treatments we have today were developed as a result of past research studies. It can take a long time for some research results to impact care. This means that research from this project may not directly influence your care or benefit you personally. However, your participation may contribute to improved healthcare in the future. You will not receive money if research leads to a new test, treatment, medicine, or medical device.

Are there any risks to me or others if I take part in the biobank?

Data privacy: Your privacy is very important to us. Every effort will be made to protect your privacy. If you agree to take part, your samples and healthcare data will be coded with a unique biobank code number e.g., 0001 instead of your name to reduce the risk of any accidental or unlawful disclosure of your healthcare data.

Your coded samples will be stored in a secure freezer at the Tallaght University Hospital Research Laboratory under the direction of Dr John R. Kelly and then transferred to the TCIN laboratory located at Trinity College Dublin, for further analysis, under the direction of Prof. Andrew Harkin.

Sample donation: There are small risks associated with sample donation. These risks are rare and mostly related to normal blood sample taking, such as dizziness, fainting, and bruising and/or swelling and/or infection at the site of the injection. Should you experience any symptoms, please let (hospital personnel) know. Unexpected adverse events, such as thrombosis (clot) of the vein due to trauma and infection which results in thrombophlebitis are extremely rare.

PART 2 – DATA PROTECTION

Who is responsible for the information and samples you provide (i.e., the data controller(s))?

Tallaght University Hospital and the Health Service Executive (HSE) are responsible for the healthcare information in your medical records. Trinity College Dublin and Tallaght University Hospital are the lead institutions for the Depression Biobank and have overall responsibility for running the biobank.

How long will you keep the samples and data?

If you consent to providing your samples for biobanking, your samples and healthcare data may be included in many Depression research studies. Researchers will not be able to identify you. Your name will be replaced with a code by hospital personnel. All data and samples are identified by this code and not your name.

Researchers can always learn from your healthcare data even after all samples have been used. For this reason, your data may be stored indefinitely (forever). Samples in the biobank will remain frozen for decades and potentially indefinitely, so that they can be used for future research studies into Depression or related diseases. We would like to keep the data this long as scientific research is changing and advancing all the time, and we do not yet know what kinds of research questions will arise in the future.

These samples will be used by us and other academic researchers who can make discoveries which identify the possibility of new medicines and treatments. Due to high-costs and the expertise involved, health-related companies must build on these discoveries to deliver these new medicines and treatments for patients.

We will ask you to choose who you are happy to share your samples and data with for approved research studies in the consent form.

Who will access and use my personal data as part of this biobank?

Dr John R. Kelly will access your medical records. The blood sample identified by code only will be analysed by Prof. Andrew Harkin in TCIN.

How can other researchers access the samples or data?

To access the samples and/or data held by TCD, researchers must follow the process outlined below.

We have developed strict procedures for who can access the data and samples. We call this governance. In order to access data or samples, researchers must:

1. Apply to the Steering Committee (John R. Kelly, Andrew Harkin, Claire Gillan) and
2. Get ethical approval from an independent research ethics committee; and
3. Sign and adhere to a legal contract outlining how the data and/or samples are to be used and kept confidential.

This 3-step process is the same whether the researcher works for a university or a health-related commercial company and ensures that sharing is limited to research which is in the wider public interest. Any use of your samples and healthcare data must respect the consent that you have given.

How will information be kept confidential?

Samples stored in the biobank will be identified by a biobank number. The key to this number code and any personal information will be kept confidentially by Dr John R. Kelly. You will not be identified in any presentation or publication emanating from this biobank.

What is the lawful basis to use my personal data?

We will only use and or share your coded healthcare data and samples for approved research projects, to help advance scientific research on Depression. This is in line with Article 6(1)(e) and 9(2)(j) of GDPR.

What are my rights?

- You can request access to the data held, and you can ask to receive a copy of that data.
- You can request restriction of the use of your data.
- You can object to the use of your data, and any further use.
- You can request that inaccurate information about you is corrected.
- You can request deletion of your data.

You can request any of the above unless the request would make it impossible or very difficult to conduct the research. (For example, if research is about to be published).

You can exercise these rights by contacting Dr John R. Kelly.

PART 3 – COSTS, FUNDING & APPROVAL

Will it cost me anything if I agree to take part?

No. It will not cost you anything to take part. We are not directly paying participants to take part in the biobank. However, participants may receive a small voucher as a token of appreciation for their time and contribution.

Who is funding this biobank?

The project has been funded by the Health Research Board (HRB) for the first four years. We may also receive additional funding through research collaborations using your data and samples. However, these funds will be used to maintain and improve the biobank infrastructure and staffing. This is a not-for-profit biobank, established in the public interest to improve healthcare outcomes.

Has this biobank been approved by a research ethics committee?

Yes. This biobank has been approved by the St. James's and Tallaght Hospital Ethics Committee (Project ID: 0037).

PART 4 – FURTHER INFORMATION

Where can I get further information?

Principal investigator & Data Controller:

Dr John R. Kelly, Consultant Psychiatrist and Associate Professor in Psychiatry, Trinity College Dublin, Trinity Centre for Health Sciences, Tallaght University Hospital, D24 NROA, (01) 463 5200, kellyj37@tcd.ie

What happens if I wish to make a complaint?

Please contact the principal investigator Dr John R. Kelly.

Will I be contacted again?

Yes. You may be contacted in the future by our research team, if there are any clinically relevant results, or to discuss future research.

5 – KEY WORDS

When we say...	We mean...
Academic research	Research which is carried out in hospitals, universities, colleges, and research institutes.
Biobank	A large collection of biological samples and healthcare data, donated by people for health research.
Biological samples ('samples')	Samples donated by people for research. Samples included but not limited to blood, urine or tissue that is not required for diagnosis. These samples are Coded before being shared. Researchers are only given access to Coded samples.
Coded	This is where information that might identify you (such as your name) has been replaced with a unique code (for example - 001). This means you cannot be directly identified from the information.



DNA	DNA stands for deoxyribonucleic acid, which is a molecule that makes up genes and contains the instructions a living thing needs to develop, live and reproduce. These instructions are passed down from parents to their children. You can read more about DNA at https://www.genome.gov/genetics-glossary/Deoxyribonucleic-Acid
GDPR	This stands for “General Data Protection Regulation”. It is a European data protection law that gives individuals more control over their personal information.
Genomic research	Research which examines peoples’ genetic information (genes) to help us understand Depression. You can read more about genomics at https://www.genome.gov/genetics-glossary/genomics
Healthcare data	Health Information which may be taken from your hospital chart, hospital electronic patient record, other hospital databases and/or may have been shared from your GP record to the hospital where you were recruited. It includes for example your treatments, test results, images/scans, family medical history, and health-related lifestyle data.
Health research regulations	In Ireland there is specific legislation that gives individual more control over their personal information used for health research.
Health-related commercial companies	Businesses which develop and sell new diagnostic tests, treatments, medicines, medical devices, for profit. Examples are start-ups, academic spin-out companies, diagnostic and biopharmaceutical companies.
Identifiable data	This is information that may identify you, such as your name, address, date of birth, hospital number, medical record number or electronic record number
Principal Investigator	The person responsible for a biobank or specific research biobank, for example, a researcher, a hospital consultant, or a hospital doctor.
Proteins	Proteins are molecules that play many critical roles in our body. They do most of the work in cells and are required for the structure, function, and regulation of the body’s tissues and organs. The instructions for how our body makes protein is encoded in our DNA. You can read more about proteins at https://www.genome.gov/genetics-glossary/Protein



Research Ethics Committee (REC)	This is an independent group of people with the experience and skills to review a proposed research biobank, to ensure that research is carried out ethically and safely and that your rights are protected. A Research Ethics Committee is the acknowledged international best practice structure for overseeing the conduct of ethical standards in healthcare research.
Research Biobank	This is a biobank that researches the processes involved in health and disease. Research studies involving this biobank would be to learn more about Depression such as the causes, and how Depression evolves and will support the development of new strategies for prevention, diagnosis and treatment.
Researchers	The scientists, doctors, nurses and other healthcare professionals doing Depression research. They may come from hospitals, universities, research institutes or health-related companies.
RNA	RNA stands for ribonucleic acid. RNA plays an important role in how our cells make proteins from the instructions in our genes. You can read more about RNA at https://www.genome.gov/genetics-glossary/RNA-Ribonucleic-Acid
Steering Committee	This is a committee of the investigators. The role of this committee is to decide “why” and “how” the Biobank samples/and or data are used and by whom.