Appendix 3

University of Cambridge

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**Participant information sheet**

Title of Project: A survey study of delirium and Lewy body associated features in people with a diagnosis of Lewy Body Dementia.

Name of Researchers: Dr. James FitzGerald; Dr. Annabel Price and Prof. John O’ Brien

Thank you very much for expressing interest in the above-named study. You are invited to participate in a survey study which explores the features of dementia and delirium. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you.

**What is Lewy body dementia and Alzheimers disease dementia?**

Lewy Body dementia and Alzheimers disease dementia are complex and common forms of dementia. As a dementia, it affects a wide variety of brain functions which include, thinking, attention, sleeping, and perception. Overall, it makes life very difficult for people and their families. Lewy body dementia is difficult to diagnose and often appears like other forms of dementia (Alzheimers disease dementia) and similar medical problems, such as delirium (acute confusion).

**What is delirium?**

Delirium is a sudden, temporary episode during which there is reduced memory and awareness of surroundings during a physical illness. There are many different symptoms such as confusion, agitation, hallucinations (seeing things that are not there) and poor sleeping, and it can vary in severity from day to day. Common causes of delirium include infections, some medications and dehydration.

**Why are we doing this study?**

Delirium is common in people with dementia, especially Lewy body dementia, and can sometimes be the first presentation. We wish to see if there are differences between people with delirium who later develop Lewy body dementia and people who do not have episodes of delirium but later develop Lewy Body dementia. In our study, we hope to identify early signs of delirium and Lewy body dementia, assess the impact of delirium on patients and carers, and examine ways to improve its detection. We hope that this will lead to better detection/diagnosis and treatment of delirium and Lewy body dementia in the UK. We also aim to compare these findings to individuals with Alzheimers disease dementia.

**Why am I being considered for this study?**

We understand that you are either a carer, relative or close friend of a person with a diagnosis of either Lewy body dementia or Alzheimers disease dementia, and this is why you are being asked to take part in the study. To fully understand delirium and dementia, we need to study a large number of participants, therefore every participant is very important to us.

**What does the study involve?**

The study involves a single telephone interview with us asking you some questions about the person you are caring for, their symptoms and when they began. This should take less than 30 minutes. We would telephone you at a pre-arranged time that suits you, and while we would usually do the interview on a single occasion, if you preferred we could do this as two (or more) shorter calls.

**What are the areas that will be discussed during the survey?**

The questions asked during the survey will focus on how dementia affects the person. It will touch upon their symptoms, how these developed, whether they have had admissions to hospital, if they developed delirium, and what was the cause(s) of this presentation where it is known.

**Will all details be confidential?**

Yes, only researchers involved in the research study as stated above will have access to the data. The survey details will be stored and protected in keeping with University of Cambridge research authorities. However, this confidentiality may be breached if safeguarding concerns such as situations involving harm or likely harm are disclosed.

**Is there any risk?**

The study only involves being asked some questions during the phone survey and there will be no procedures and therefore, no risk to you. We will stop the interview at any time if you wish to stop. In addition participants can withdraw data up to the point of analysis.

**What should I do if I am interested?**

If you would like to take part in the study, please let us know by signing and returning the consent form which, along with this information sheet, you should already have. If not, please contact **Dr. James FitzGerald (details below)**. If you have any further questions, please contact James by email or phone before signing the form. If you have no further questions and are happy to take part, please sign and date the consent form and return in the envelope provided. We will then contact you to arrange the telephone interview.

**Contact: Dr. James FitzGerald**

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**Joint sponsor PIS statement**

Cambridgeshire and Peterborough NHS Foundation Trust and the University of Cambridge and are joint sponsors for this study based in the United Kingdom. Cambridgeshire and Peterborough NHS Foundation, Cambridge University Hospital (CUH) and the University of Cambridge will be using information from you in order to undertake this study and will act as joint data controllers/processors. This means that these organisations are responsible for looking after your information and using it properly. The University of Cambridge will keep identifiable information about you for 5 years after the study has finished. Cambridgeshire and Peterborough NHS Foundation will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information using the following links:

<https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/>

<https://www.cpft.nhs.uk/about-us/privacy.htm>

***Thank you for reading this leaflet.***

***We deeply appreciate your interest and time.***