PRIVACY NOTICE -THE MABEL STUDY

I have questions or want further information. Who do I talk to?

If you have any questions or concerns about how your data will be processed within this project please contact Hull Health Trials Unit (HHTU) in the first instance:

- Email: hhtuenquiries@hyms.ac.uk
- Telephone: 01482 463444
- Address: 3rd Floor, Allam Medical Building, University of Hull, Hull, HU6 7RX

If you would like further information, please contact the University of Hull, Data Protection Officer (DPO):

- Email: dataprotection@hull.ac.uk
- Telephone: 01482 466594
- Address: University of Hull, Cottingham Road, Hull HU6 7RX

[Note: University of Hull staff are currently working from home due to COVID-19 and will respond to queries as soon as we can. You can email or post queries to the above contacts]

What is this project about?

Chronic breathlessness affects most people with advanced lung and heart disease, often disabling despite best treatments of the underlying condition(s). Studies of regular, low doses of "long-acting" morphine over a few days have been shown to help reduce chronic breathlessness safely. However, we do not know the effect in the longer term. We will test how well long-acting morphine works in reducing symptoms of chronic breathlessness in this study. If proved safe and helpful, clinicians will be able to offer patients a more effective way to improve symptoms and quality of life for patients living with chronic breathlessness.

This randomised controlled, blinded drug study aims to recruit 158 people to find out if regular, low dose morphine (one capsule taken twice daily for two months), is better than identical placebo (dummy) doses for chronic breathlessness. People with underlying cardiac, respiratory, cancer or post COVID-19 chronic breathlessness who have agreed to participate in the study will be randomly selected to take either morphine or placebo.

After two weeks, there is an option to increase the dose if breathlessness has not improved on the lower dose as long as side-effects are well managed and tolerable. At the end of the study participants may continue to take Open Label (not a placebo dose) morphine as part of their usual care via their GP.

We will measure the effectiveness of morphine on chronic breathlessness by asking participants to complete several questionnaires at various time points during the study. The key indicator of success will be based on how participants score their experience of 'worst' breathlessness in the previous 24 hour period compared to baseline.

Other measures will include: physical activity, quality of life, sleep quality, morphine side-effects, overall ability to function and healthcare service utilisation.

An additional element of the study is to ask the participant's main carer to complete a questionnaire about the impact that caring has on them. Should a participant die while on the

study, carers may be approached a few months later to complete a bereavement questionnaire. Carers can opt out of this aspect of the study if they so wish.

To ensure that the prescribing of morphine to patients with chronic breathlessness is implemented after this study (if proved effective), we will conduct clinician training sessions. Clinicians, carers and study participants will be invited to discuss issues that would influence their decision to prescribe, support or administer morphine use for chronic breathlessness. If morphine is shown to help and is safe to take (i.e. does no harm), we want all eligible patients to have access to it and used in accordance with the best evidence available.

What data are you using?

We will use data generated from the study questionnaires, data collection forms, your medical records and an Activity Monitor called an ActiGraph. The data collected will be entered into a database by your local research team. Personal details that can be used to identify you will be removed and all your study documents will be assigned a unique pseudonymised Subject Identification Number.

The team responsible for analysing the data will not be able to identify you from any of the information in the database. Only your local research team will be able to link your data to the unique Subject Identification Number. Team members from HHTU and regulatory organisations responsible for monitoring the study for data quality and compliance may request permission to review your medical and research records to check the accuracy of the data collected.

How will you look after the data?

Your data will be managed and stored by HHTU using their data capture system REDCap cloud and BOX Governance file storage system. Both systems have high levels of security and all data is stored within the EU. Only staff working on this study will have access to your data. Staff have individual logins and all activity is logged. The HHTU has a Data Security and Protection Toolkit (DSP) which provides assurance that we are practising good data security and that personal data is handled correctly. More information about the DSP can be found here.

If you provide consent electronically, this information will have been collected using DocuSign.

Data collected on hard copies will remain at the hospital in a secured cupboard and will remain under the control of the clinical staff.

How long will you keep it?

We will keep your data as archived records for 15 years in compliance with drug study regulations.

What is the purpose of the General Data Protection Regulations (GDPR 2018)?

Under the GDPR 2018, there is a legal basis for processing the personal data we collect about you during research as this is being done in the public interest (schedule 6) and for scientific research purposes (schedule 9).

The University of Hull (UoH) is the data controller of the information it collects and processes as described in this Notice. This means that it has the core legal responsibility to safeguard the information and ensure it is processed lawfully. The law is set out in the EU General Data Protection Regulation (called "GDPR") and a new UK law, the Data Protection Act 2018. In particular UoH must:

- Take steps to ensure that the data it processes is accurate and up to date;
- Give you clear information about its processing of your data, in one or more privacy notices like this one and the participant information sheet (referred to together in this section as a "Privacy Notice");
- Only process your data for specific purposes described to you in a Privacy Notice, and only share your data with third parties as provided for in a Privacy Notice; and
- Keep your data secure.

The law states that we can only process your personal data if the processing meets one of the conditions of processing in Article 6 GDPR. As we are processing your special category data we also must meet one of the conditions in Article 9 GDPR. Special Category data includes personal data which relates to your ethnicity, sex life or sexual orientation, health or disability, biometric or genetic data, religious or philosophical beliefs, political opinions or trade union membership. Under the data protection legislation, we need to explain the legal basis for holding your data, i.e. which of these conditions apply.

For our research project the following conditions apply:

• Article 6.1(e) of the GDPR, i.e. our processing is necessary for the performance of a task carried out in the public interest. Research is a task that UoH performs in the public interest, as part of our core function as a university;

• Article 9.2(j) of the GDPR, i.e. our processing is necessary for research purposes or statistical purposes. This condition applies as long as we are applying appropriate protections to keep your data secure and safeguard your interests.

Your rights as a data subject

Under the data protection laws, you have a number of rights in relation to the processing of your data. These are limited by the lawful basis under which we hold your data. Your rights are:

- Right to request access to your data as processed by UoH and information about that processing
- Right to rectify any inaccuracies in your data
- Right to place restrictions on our processing of your data

If you would like to exercise any of your rights as outlined above, you can contact the DPO as above or visit the Data Protection page on our website: Available here.

We will always aim to respond clearly and fully to any concerns you have about our processing and requests to exercise the rights set out above. However, as a data subject, if you have concerns about our data processing or consider that we have failed to comply with the data protection legislation, then you have the right to lodge a complaint with the data protection regulator, the Information Commissioner:

Online reporting: https://ico.org.uk/concerns/

Email: casework@ico.org.uk

Tel: 0303 123 1113

Post: Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF