# Participant Information Sheet (PIS)

**Study title**

Patient real world handling of protein medications– a smart label study

**Chief Investigator**

Professor Isla Mackenzie, Professor of Cardiovascular Medicine and Honorary Consultant Physician, University of Dundee and Ninewells Hospital, Dundee.

IRAS ID: 331245

**Invitation to participate.**

We would like to invite you to take part in a research study.

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve for you.

Please take the time to read this information sheet carefully. You can ask us any questions you have. You can also discuss this study with other people such as your family or your family doctor (GP). If you decide to participate in this study, you will be asked to sign and date a consent form. You will receive a copy of the signed form.

This information sheet is in two parts:

Part 1 tells you the purpose of the study and what we would ask you to do if you take part.

Part 2 gives more detailed information about the conduct of the study.

## Part 1

## About the study and your participation

### Background to the study

How medicines are stored, transported and used can affect their quality and how well the medicine works. Medicines can be affected by how much light or moisture they are exposed to as well as at what temperature they are stored, and any vibrations they experience. Medicine manufacturers provide hospitals, pharmacists, doctors, nurses and patients with guidance on how best to store, transport and use their medicines. However, there is a lack of knowledge about what really happens to medicines when they leave the manufacturer.

By taking part in this study you can help us understand what happens to people's medicines after they leave the pharmacy or supplier.

This study is part of a wider research project – RealHOPE – which is being undertaken by a group of universities, research institutes and companies across Europe to improve our knowledge of this area and create educational resources to help both health professionals and patients (https://realhope.se).

### What is the purpose of this research?

We are doing this research because we want to understand better what happens to people's medicines once patients have collected them from a pharmacy or they have been delivered to the patient at home. We are particularly interested in what happens to a group of medicines called protein medicines which are used to treat a wide number of health conditions (for example insulin in diabetes, some treatments for inflammatory conditions, skin conditions and other health problems). We are interested in protein medicines in particular because these medicines may be more prone to being affected by how and where they are stored and how they are transported. Using a credit-card sized smart label containing sensors, which will be attached to medication packaging, this study will investigate how much light and moisture the medicine is exposed to as well as what temperature, movements and vibrations it experiences during normal storage and handling by patients.

We intend to recruit approximately 20 participants for this study.

### Why have I been invited?

You have been invited because we think that you may currently be using a protein medicine and you have expressed interest to your doctor or nurse in being contacted with more information.

### Do I have to take part?

It is up to you to decide whether or not to take part. Participation in this study is entirely voluntary. If you do start the process, you are then free to withdraw at

any time, without having to give a reason and without this affecting your future medical care or your relationship with medical or nursing staff looking after you.

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

If you are interested in taking part in this study, we will arrange an appointment with a member of the study team (nurse, pharmacist or doctor), usually at the Hypertension Research Centre at Ninewells Hospital. This appointment should take approximately an hour and will be arranged for the day when you will be collecting your medicine from the pharmacy or just before you are expecting to have it delivered to your home.

At your appointment a member of the study team will discuss the study with you and answer any questions you may have. If you decide that you would like to take part, you will be asked to sign a consent form. You will then be asked some questions about yourself, the health condition you are taking the protein medicine for and what medicine you take and your answers will be noted.

The smart label that will measure what happens to your medicine will be activated at your visit. If you have your medicine with you, the smart label will be attached to your medicine packaging at your visit. If you do not have your medicine with you, you will be given the activated smart label to take away with you and given instructions about how to attach it to your medicine packaging.


The smart label is a credit-card sized label that has a battery and sensors to detect movement, humidity, light and temperature over a period of approximately 2-4 weeks. The labels are being manufactured and provided for this study by CPI (Centre for Process Innovation). This records any environmental exposures that your medicine packet encounters during normal transport, storage and use. Data on these exposures is extracted from the label at the end of the measurement period. It will be analysed to look for any events of interest. Usually, the data can be extracted by the study team in Dundee when you return the label. If for any reason, the battery life runs out before the data is extracted, we may need to send your label to CPI (the company in England who makes the labels) and ask them to extract the data from your label. They would not receive any identifying information about you, only the labels and the data contained on these. Once extracted, the anonymised data (without your identifying details) may be shared with other members of the RealHOPE project, including in other countries within

Europe for analysis. Again, none of your identifying details such as name or date of birth will be shared with other partners outside the Dundee study team.

You will also be given a study diary to take home and complete. You will be asked to use this diary to record anything unexpected that happens to your medicine, for example if you dropped it. We will also ask you to record the date and time you collected or received your medicine and the dates and times when you used it. You will be given clear instructions about what information you need to record in your diary.

Approximately 2 to 4 weeks later you will be asked to attend another short study visit lasting around 30 minutes to return the used smart label and your study diary to the study team. Alternatively, we can arrange for a member of staff to collect them from you if you prefer.

If for any technical or other reason it is not possible to extract the data from the smart label then you might be asked to repeat the process. If this is the case you will be issued with a new smart label and participant diary to complete. You will not need to sign another consent form.

**What are the possible benefits of taking part?**

Your participation in this study will not have any direct benefit for you but it will help us to learn about what environmental factors people's protein medicines are exposed to during normal use. The information that we learn in this study will be used to help produce educational information for patients and health professionals such as nurses, pharmacists and doctors to improve the handling of protein medicines in future.

**What are the possible disadvantages and risks of taking part?**

We do not think that there are any risks in taking part in this study. It will take up some of your time completing the diary and attending study visits. Reasonable travel expenses for attending study visits will be available upon request.

**Will my taking part in the study be kept confidential?**

Your participation in this study will not be disclosed to anyone other than the organisations or individuals described in the participant information sheet for the specific and limited purposes explained herein. People who do not need to know who you are will not be able to see your identifiable information.

**Who is funding the study?**

This study is funded by the Innovative Medicines Initiative 2 Joint Undertaking as part of the Real World Handling of Protein Drugs- Exploration, Evaluation and Education (RealHOPE) programme of work. (https://realhope.se)

**Who is sponsoring the study?**

The study is sponsored by the University of Dundee.

**Contact details?**

If you have any problems, concerns or other questions about this study, you can contact the study team by writing to MEMO Research, University of Dundee, Level 7, Ninewells Hospital, Dundee DD1 9SY, telephoning 01382 383119 or emailing memo-info@dundee.ac.uk

This completes Part 1 of the information sheet.

If the information in Part 1 has interested you and you are considering taking part please continue to read the additional information in Part 2 before making any decision.

## PART 2
## Detailed information about the conduct of the study

**What will happen if I don't want to carry on with the study?**
You can withdraw from the study at any time without giving a reason. This can be done by contacting the study team. Your medical care and legal rights will not be affected by this.

**What will happen to the results of the research study?**
The results may be presented at medical or scientific meetings, published in a peer-reviewed medical or scientific journal and in reports for the RealHOPE programme of work. You will not be individually identified in any report/publication. Any personal details will be kept strictly confidential and no information will be given in any publications through which you can be identified.

When the results have been analysed we will send you a summary of the findings. This summary will not contain any information through which you can be identified.

**Who is organising the research?**
MEMO Research at the University of Dundee is organising this study. No member of the research team is being directly paid for including you in this study.

**How will we use information about you?**
We will need to use information about you for this study.
This information will include your initials, name, address, postcode, telephone number, email address, date of birth, community health index number or CHI (the unique 10 digit identifier number used on all health care records and NHS letters to patients in Scotland). Study staff will use this information if we need to contact you. We will also let your GP know you are taking part in this study.

People who do not need to know who you are will not be able to see your identifiable information. Your data will have a code number allocated instead. We will keep all information about you safe and secure.
For the purposes of checking that we are conducting the study properly in compliance with the regulations for research, monitors from the University of Dundee or regulatory authorities may need to examine your study records.
Once we have finished the study, we will keep the data for 5 years so we can check the results in the future if required. We will write our study reports in a way that ensures no one can be identified.

**What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have up to that date.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't always be able to let you change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients
- by reading the privacy policy at the end of this document and available at https://www.memoresearch.com/
- by sending an email to dataprotection@dundee.ac.uk

**What if something goes wrong with my study participation?**

If you are concerned about your participation in the study, you have the right to discuss your concern with a researcher involved in carrying out the study or a doctor involved in your care.
If you have a complaint about your participation in the study, first of all you should talk to a researcher involved in the study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for the University of Dundee. You can find further details on how to do this here: https://www.dundee.ac.uk/governance/dca/complaints/

Additional contact information:
Directorate of Academic and Corporate Governance
University of Dundee
Nethergate
Dundee
DD1 4HN
Phone: +44 (0)1382 383000
Email: complaintsresolution@dundee.ac.uk

We do not think that participation in this study is likely to cause any harm. However, if you think you have come to harm due to taking part in the study, there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice, but you might have to pay for your legal costs.

**Insurance**

The University of Dundee is sponsoring the study in the UK and it has a policy of

public liability insurance, which provides legal liability to cover damages, costs and expenses of claims.
If you apply for health, life, travel or income protection insurance you may be asked questions about your health. These questions might include questions about any medical conditions you have or have had in the past. You might also be asked if you have had any genetic tests or about taking part in this study. We do not expect that taking part in the present study will adversely affect your ability to buy insurance as we are simply collecting data on what happens to your medicine. Your insurer may take into account any medical conditions you have, including any which are diagnosed as part of a research study/trial, when deciding whether to offer insurance to you, but we will not disclose any data without your express consent.

**Who has reviewed this trial/study?**

This study has been reviewed and given a favourable opinion by the East Midlands - Nottingham 2 Research Ethics Committee who are responsible for reviewing research which is conducted in humans.

**Contact details for further information.**

If you have any queries about this study, please contact us by writing to MEMO Research, University of Dundee, Level 7, Ninewells Hospital, Dundee DD1 9SY, telephoning 01382 383119 or emailing memo-info@dundee.ac.uk

**Thank you for taking the time to read this information sheet and for considering taking part in this study.**