



General Data Protection Regulation (GDPR) Participant Information

POP Trial

The EU General Data Protection Regulation (GDPR), along with the new UK Data Protection Act, will govern the processing (holding or use) of personal data in the UK.

You are receiving this as you are currently a participant on this clinical research study. The information below details what data is held about you and who holds or stores this.

Pledpharma AB (Grev Turegatan 11C, SE-114 46 Stockholm, Sweden) is the sponsor for this study based in the United Kingdom. NHS Lothian will collect the data and it will be stored in a secure database by the University of Edinburgh. The University of Edinburgh will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Edinburgh and NHS Lothian 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.

Providing personal data directly e.g. verbally, in a questionnaire or from your care provider

NHS Lothian will keep your episode number (e-number) from your hospital admission in order to identify you from your medical records and will not pass this information to Pledpharma AB or the University of Edinburgh. NHS Lothian will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals working on behalf of Pledpharma AB or University of Edinburgh and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Pledpharma AB and University of Edinburgh will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, episode number or contact details.

NHS Lothian will keep identifiable information about you from this study for 5 years after the study has finished.

Providing personal data indirectly e.g. from your medical records

University of Edinburgh and Pledpharma AB will collect health information about you for this research study from your medical notes. NHS Lothian will not provide any identifying information about you to University of Edinburgh or Pledpharma AB. We will use this health information to answer the research question for this study.

Use of data for future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](#).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Contact for further information

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; <https://www.hra.nhs.uk/information-about-patients/>.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at <https://ico.org.uk/>.

Data Protection Officer contact information:

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