

Privacy notice for Physio4FMD trial participants

Version 1.2, 01 February 2023

The following information is intended for participants enrolled in the Physio4FMD trial (who we will refer to as “you/your”) to explain how your personal data will be processed and looked after. Here after we will refer to Physio4FMD as the “trial”.

Who are we?

St George’s University of London is the “Controller” of the personal data that you provide us with and is registered with the Information Commissioner’s Office (ICO) for the purposes of UK data protection legislation, registration number Z5770328.

The Physio4FMD trial is sponsored by St George’s University of London and led by Dr Glenn Nielsen, St George’s University of London, Cranmer Terrace, London SW17 0RE.

The trial team includes Priment Clinical Trials Unit at University College London (UCL). Priment CTU, UCL Medical School, Upper 3rd Floor, Royal Free Campus, Rowland Hill Street, London, NW3 2PF. They are the data “Processors”. This means that they will analyse the trial data, under the instruction of St George’s University of London.

How to contact us

If you have any questions, please contact a member of the Physio4FMD trial team in the first instance:

Beatriz Santana Suárez
Email: bsantana@sgul.ac.uk
Tel: 020 8266 6468

Glenn Nielsen
Email: gnielsen@sgul.ac.uk
Tel: 0208 266 6848

If you feel you need additional advice, the University has a Data Protection Officer who can be contacted at:

Email: dataprotection@sgul.ac.uk
Tel: 020 8725 0668

Address: Data Protection Officer, Information Services, St George’s University of London, Cranmer Terrace, LONDON SW17 0RE

Background to the research

Physio4FMD is a trial of physiotherapy for functional motor disorder. Prior to taking part in the trial, all participants were given an information leaflet which explained what the research involves. You can find a copy of the leaflet [here](#). After discussing the trial with a member of the research team, participants signed their consent to participate.

Why we are collecting your personal data

We are asking you to share personal data as part of the trial to help us understand if physiotherapy is a useful treatment for functional motor disorder. Two important questions we are asking are:

1. Does specialist physiotherapy reduce physical disability (difficulty moving and walking) caused by functional motor disorder?
2. Does specialist physiotherapy lead to a reduction in the cost of functional motor disorder (both cost to the individual and cost to the NHS)?

What is our legal status for collecting research data?

As a publicly funded organisation we have to ensure that it is a task in the public interest when we use personally identifiable information from people who take part in one of our research projects. This is known as our “legal basis” for the collection and processing of personal data under current data protection regulations (Article 6 GDPR).

Due to the sensitive nature of healthcare information, it is further categorised under current data protection regulations as special category data. Where we collect this type of data we do so legally when “the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes...” (Article 9 GDPR).

How your personal data is collected

As a research participant you have shared with us information about you. This is known as your personal data. The information you have shared about your health is considered sensitive data. You have shared this information with us in-person when you first signed up to the trial; and we asked you to share follow-up information by post, telephone or an online form.

We also collect information about you held by NHS England / NHS Scotland regarding the number of hospital appointments you have had during the study 24-month period (12-months before signing up and 12-months after signing up to the trial). We will also be accessing information relating to why you attended hospital (e.g. the diagnosis resulting from attendance).

- As part of the process of requesting this data from NHS England / NHS Scotland, we will share with them your NHS number (CHI number for NHS Scotland) and date of birth, along with the Physio4FMD study code that we assigned to you. This information will be shared by a secure file transfer.
- Due to the technical complexities of accessing this data, if you were recruited from a hospital in England, 6 years’ worth of information (2017/18 to 2022/23) will be requested from NHS England.
- St George’s University of London are the “controller” of this data, the Physio4FMD research team at UCL Priment Clinical Trials Unit will “process” (analyse) this data (on the instructions of St George’s University of London).

This information will enable our health economists to calculate the costs of functional motor disorder.

How we keep your data safe

We must ensure there are safeguards in place when we use your personal and or sensitive data in our research projects. These include:

- Policies and procedures advising our researchers and staff on how to design studies and how to collect and manage your data appropriately
- Training to ensure our researchers and staff understand the importance of data protection and integrity
- Ensuring we have effective, safe and secure physical locations to store and archive research data
- Ensuring all research undertaken is appropriately scrutinised by an ethics and / or regulatory body in accordance with the UK Policy Framework for Health and Social Care Research
- Ensuring we have contractual arrangements in place with any 3rd party organisations (within or outside the EU) responsible for managing and or processing research data

Information about you that we will collect from NHS England / NHS Scotland will be transferred into a Data Safe Haven (a secure way to store digital information) maintained by University College London. Only named Priment Clinical Trials Unit employees working on the trial will have access to this data.

Who we share your data with

We will not share your personal data with anyone outside the research team.

The Priment Clinical Trials Unit (who will analyse the trial data) will only have access to pseudonymised data. This means that your name is replaced with a unique study code. The key to this code is only held at St George's University of London.

Anonymised data (data that cannot be connected to you) may be shared with researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](#).

Where we publish the results of any research it will contain no identifiable information.

How long we keep your information for?

Research data will be kept for as long as it is required, to meet the objectives of the research project, and / or to meet the legal and/or ethical requirements under vigorous regulations governing clinical research. For the Physio4FMD trial, we will keep your personal data for 10 years. It is important for us to retain research data so that we are able to refer back to it to ensure the integrity of the project, and that the safety of the participants is maintained.

What are your rights?

The UK General Data Protection Regulation (GDPR) provides the following rights for individuals:

1. The right to be informed
2. The right of access
3. The right to rectification
4. The right to erasure
5. The right to restrict processing
6. The right to data portability
7. The right to object
8. Rights in relation to automated decision making and profiling.

You can read more about what this actually means here: <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/>

The Physio4FMD trial is carried out in the public interest. Therefore, your rights to access, change or move your information are limited. This is because we need to manage the data in specific ways in order for the research to be reliable and accurate.

If you withdraw your consent to participate in this research, this will not mean we will have to remove all data as well. We will keep the information about you that we have already obtained to ensure research integrity is maintained in the public's interest. To safeguard your rights, we will strive to use the minimum personally identifiable information possible.

If you wish to act on any of your rights, or require further information about your rights, please contact us.

How to make a complaint

If you are unhappy with the way in which your personal data is being processed you may, in the first instance, lodge a complaint with the University Data Protection Officer using the contact details above.

If you continue to have concerns thereafter you have the right to contact the Information Commissioner for a decision. The Information Commissioner can be contacted as below.

Helpline: 0303 123 1113

Website: <https://ico.org.uk/for-the-public/raising-concerns/>

Changes to this notice

We may update this Privacy Notice from time to time. We will notify you of the changes where we are required by law to do so, and document changes on this website.

| Date of Change | Changes Made |
|----------------|--|
| 01/02/2023 | <p>The following additions were made under the section, How your personal data is collected</p> <ul style="list-style-type: none">• As part of the process of requesting this data from NHS England / NHS Scotland, we will share with them your NHS number (CHI number for NHS Scotland) and date of birth, along with the Physio4FMD study code that we assigned to you. This information will be shared by a secure file transfer.• Due to the technical complexities of accessing this data, if you were recruited from a hospital in England, 6 years' worth of information (2017/18 to 2022/23) will be requested from NHS England.• St George's University of London are the "controller" of this data, the Physio4FMD research team at UCL Priment Clinical Trials Unit will "process" (analyse) this data (on the instructions of St George's University of London). <p>Under the section, Who are we? (Priment Clinical Trials Unit, UCL), the following text was added</p> <ul style="list-style-type: none">• [This means that they will analyse the trial data], under the instruction of St George's University of London. <p>The organisation name "NHS Digital" was updated to "NHS England"</p> |