SIMBEC-ORION

PATIENTS' GUIDE for INDEPENDENT HEALTHCARE SETTINGS

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SECTION 1 – SUMMARY OF STATEMENT OF PURPOSE

Simbec-Orion is a Clinical Research Organisation conducting early phase (Phase I/II) clinical research. We conduct clinical trials of new and existing medicines on behalf of the pharmaceutical industry. We have a fully equipped purpose built clinical research unit with all of the support services to conduct clinical research.

We are accredited as a Phase I Unit by the UK government, Medicines and Healthcare products Regulatory Agency (MHRA), which regulates medicines, medical devices and blood components for transfusion in the UK.

The MHRA Phase I Accreditation scheme requirements[1] outlines that:

"*The scheme was designed to give assurance that organisations within the scheme not only met but surpassed the basic regulatory GCP aspects by having additional 'best practice' procedures that encompassed the highest standards for avoiding harm to trial participants and for handling medical emergencies should they arise. Thus also assuring sponsors that accredited organisations make significant contributions to enhancing the safety of participants and are considered to be centres of excellence for Phase I research*."

In line with our MHRA Phase I Accreditation our objective and purpose is to be a Centre of Excellence for Phase I research, having "best practice" procedures and encompassing the highest safety standards at all times.

[1] Phase 1 Accreditation Scheme Requirements

SECTION 2 – TERMS AND CONDITIONS

Simbec-Orion is a Clinical Research Organisation conducting early phase (Phase I/II) clinical research. We conduct clinical trials of new and existing medicines on behalf of the pharmaceutical industry.

All clinical trials are conducted in accordance with the study protocol, our MHRA Phase I accreditation, Good Clinical Practice and our Quality Management System. The study protocol outlines the study drug being tested and the supporting data available, the trial objectives and trial procedures. Each study protocol and all associated documents are reviewed and approved by an independent ethics committee and the MHRA prior to starting the trial. Simbec-Orion also has a management "green light" procedure to ensure all required documentation and training is in place prior to starting each clinical trial.

All Trial Participants will need to provide informed consent prior to any study procedures. The Trial Participant Information Sheet and Informed Consent and all other participant facing documents are approved by the ethics committee prior to use. Section 3 outlines the elements covered by the Trial Participant Information Sheet and Informed Consent.

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The Trial Participant Information sheet provides the Inconvenience payment and expenses for each individual trial, based on the specific trial requirements. The proposed payment and expenses are also approved by the ethics committee.

SECTION 3 – CONTRACT BETWEEN PATIENTS AND SERVICE PROVIDER

A clinical trial is used as a way of testing potential new medicines/drugs to support decision making and the drug's development. Trials are used to answer research questions. For example they may be used to assess:

- safety of the drug
- how much of the drug gets into the body/bloodstream
- effectiveness of the drug,
- comparison of two or more different medicines to find out which is most effective or safer.
- new methods of devices, diagnostic tests etc.

Trials provide us with data and information to help make decision on the correct dosage, routes of administration and the next steps in a drug development pathway.

In order for us to conduct these clinical trials we need trial participants. These participants may be healthy volunteers or they may be patients with a condition or illness. At Simbec-Orion, we have a database of people who have expressed an interest in taking part in clinical trials.

If you would like to join our database and be contacted about possible involvement in clinical trials, you will be invited in for a 'general screening' appointment. At this appointment you will have the opportunity to ask any general questions you may have about clinical research at Simbec-Orion.

For every trial that we conduct here at Simbec-Orion, we have a trial protocol. The protocol tells the researchers at Simbec-Orion what medicine is being tested in the trial, what criteria trial participants need to meet to be eligible and what procedures / tests should be performed. All of this key information is also included in laypersons terms in a Participant Information Sheet. Before we can conduct a clinical trial at Simbec-Orion, all key documents must be reviewed and approved by

- an independent group of people, called a Research Ethics Committee, to protect your interests and
- the UK government Medicines and Healthcare products Regulatory Agency (MHRA).

A medically qualified 'Investigator' is responsible for each clinical trial conducted at Simbec-Orion and leads an experienced team of researchers to conduct the trial.

How do I take part? (Informed Consent)

Once you have successfully joined our database, we will contact you if we think you might be eligible for an upcoming trial. If you are interested in taking part, you will be invited to Simbec and given the trial specific Participant Information Sheet to read, during which time you will be able to discuss this information with the team who will answer any questions you may have. This will provide you with full details of the requirements for the trial, including:

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SECTION 3 – CONTRACT BETWEEN PATIENTS AND SERVICE PROVIDER

- Invitation paragraph
- What is the purpose of the study?
- Why have I been invited?
- Do I have to take part?
- What will happen to me if I take part?
- Expenses and payment
- What is the drug being tested?
- What are the alternatives for treatment?
- What are the side effects of any treatment received when taking part and how do we decide on which dose to give in each group?
- What are the other possible disadvantages and risks of taking part?
- What are the possible benefits of taking part?
- What if relevant new information becomes available?
- What will happen if I don't want to carry on with the study?
- What if there is a problem and I wish to make an insurance claim?
- Will my taking part in this study be kept confidential?
- Involvement of your GP/family doctor
- What will happen to any samples/data I give?
- Will any genetic tests be done?
- What will happen to the results of the study?
- Who has reviewed the study?
- Who is organising and funding the research?
- Further information and contact details

Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. You will be given time to read the information carefully and discuss it with your friends and relatives.

If you are happy with all of the information provides, you will be asked to sign a trial consent form to confirm your consent to take part and that you understand the information provided to you. It is up to you to decide whether or not to take part. You are still free to withdraw at any time and without giving a reason.

How will my privacy and dignity be protected?

You will undergo screening procedures individually in a designated room. You may ask for a chaperone at any time.

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SECTION 3 – CONTRACT BETWEEN PATIENTS AND SERVICE PROVIDER

Each bed area in the wards has a curtain that can be drawn around it offering privacy and you will sleep in a ward with volunteers of the same sex. Toilet and shower facilities are available for male and female volunteers separately.

Simbec complies with GDPR/UK data protection laws. Your medical confidentiality will be protected and as a research participant nothing that could reveal your identity will be disclosed outside of Simbec.

All information collected about you during the course of the study will be kept strictly confidential.

SECTION 4 – COMPLAINTS PROCEDURE

We expect your time at Simbec to be a positive experience however if for any reason you are not happy with any aspect of your participation, we have a complaints procedure that is available from our Enrolment Services department.

SECTION 5 – SUMMARY OF PATIENT VIEWS

Following screening and at end of each trial, we ask our participants for feedback on their experience. This is collated and reviewed regularly by the Simbec-Orion management team to inform further improvements to the participant's experience. We are happy to provide you with more information on this feedback, on request.

SECTION 6 – REGISTRATION AUTHORITY

Simbec is regulated by Healthcare Inspectorate Wales, whose contact details are given below:
Healthcare Inspectorate Wales
Welsh Government
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ
Phone: 0300 062 8163
Fax: 0300 062 8387
E-Mail: hiw@gov.wales

A copy of our most recent Healthcare Inspectorate report can be found here: Simbec Research Ltd | Healthcare Inspectorate Wales

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SECTION 7 – PATIENT GUIDE REVIEWS

Date Patient Guide reviewed	03 September 2025
Category of changes made	☒ Change of staff details ☒ Change of Registered person(s) ☐ Change of treatments ☐ Change of setting/organisation details General updates throughout (no material changes) Addition of Registered Manager and Responsible Individual personnel names following change of details.
Reviewed by	Ceri Edwards Enrique Rafalin
Date HIW notified of changes	05 September 2025

Date Patient Guide reviewed	
Category of changes made	☐ Change of staff details ☐ Change of Registered person(s) ☐ Change of treatments ☐ Change of setting/organisation details
Reviewed by	
Date HIW notified of changes	

Date Patient Guide reviewed	
Category of changes made	☐ Change of staff details ☐ Change of Registered person(s) ☐ Change of treatments ☐ Change of setting/organisation details
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Document Approvals

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Task: Approvers Approval Verdict: Approve changes & release Approval to be made Effective	Ceri Edwards, (ceri.edwards@simbecorion.com) Approver 04-Sep-2025 11:07:23 GMT+0000

Task: QA Approval Verdict: Approve changes & release QA Approval to be made Effective	Enrique Rafalin, (enrique.rafalin@simbecorion.com) QA Approver 04-Sep-2025 11:10:34 GMT+0000