



THE BRITISH PAEDIATRIC ORPHAN LUNG DISEASE REGISTRY PATIENT INFORMATION SHEET

Please ask for a translation or interpreter if you wish

What is the BPOLD Register and why is it being set up?

BPOLD stands for British Paediatric Orphan Lung Disease. We call some very rare lung disease “Orphan” diseases because they don’t get so much care and attention as common lung disease. With a rare disease, research which might help patients may never happen because we can’t find enough patients to test a new treatment properly.

If facts about all the patients with a rare disease were gathered together, however, this would help to find out more about their disease. They could also help each other, if they wanted to, by setting up patient societies so that they could talk to other patients with the same disease. It would be possible to collect more information on which tests and treatments were helping patients most. This would help doctors who hadn’t treated many patients with the disease to look after them better.

This is the idea of the BPOLD Register. This will be a list, held on a computer, of all the patients with orphan lung disease who agree to be on it. The information is held on a special dedicated secure server. We are inviting you to be on this list.

What will happen now if I agree to be on the BPOLD Register?

Your consultant will give a small amount of information about you to the BPOLD committee to put on their computer. The only information that will go on the computer will be:

- Your hospital number
- Your initials
- Your date of birth
- The names of your consultant and your hospital
- The rare disease that you have

This is all that we are asking from you at present. We hope that the register will help research into rare disease but agreeing to have your details on the register does not mean that you have agreed to take part in any research at present. Please note especially that we can not promise that you will ever be invited to take part in research just because you have joined the BPOLD register. Being on the register simply means you are saying that you are willing to be invited to consider taking part in research in the future.

What will be done with this information and what may happen later?

From the register the British Paediatric Respiratory Society will get some idea of how many patients there are in the UK with each rare lung disease. Scientists and doctors who want to find out more about what causes a rare disease, or want to try out a new treatment, will then know if there may be enough patients with the disease for their research project to be possible. These scientists and doctors are usually called “researchers”.

The researchers would have to apply to the BPOLD committee to approve their research project. This committee will be responsible for making sure that the research project is safe, will be performed to the highest scientific standards, and is in the best interests of patients. It will also have to be approved by an ethics committee.

If the researcher’s project passes these tests the BPOLD committee will give them the details of all the patients on the register with the rare disease they want to study. These patients can then be asked if they would be willing to take part. The researchers will not be able to contact you directly because your name and address will not exist on the register. They will have to contact your consultant. He or she will know who you are from your hospital number, initials and date of birth. They will then arrange for you to be told about the research and it will then be entirely up to you whether or not you decide to take part. Being on the register would not in any way oblige you to take part in the research.

Who can see information about me on the BPOLD register?

You can ask to see a copy of your own entry on it.

Your consultant and other doctors caring for you can also ask to see your entry.

Researchers whose projects have been approved by the BPOLD committee will be allowed to see your entry if you have the disease that they want to research.

The BPOLD committee may approve some international studies. Orphan disease are so rare that there may not be enough patients in the UK, (even if they all wanted to take part), for good research to be done. Researchers in other countries may therefore ask UK patients to join patients living abroad so that there are enough patients. **If you agree to be on the BPOLD register you will therefore also be asked to give your consent to researchers from abroad being allowed to have your details.** However, the BPOLD committee will only allow this if foreign researchers meet the same standards that we expect from UK researchers.

Can I have my details taken off the Register?

Yes. If you change your mind at any time you can tell your consultant, or contact the BPOLD committee directly to have your entry removed.

You will also be given the opportunity to come off from the register when you turn 18.

Can any unauthorised person find my personal details from the BPOLD register?

No. Even if someone managed to break into the secure server's computer, they would only see encrypted information.

Do I have to take part?

No. If you don't want your name to be on the BPOLD register you don't need to do anything else. Your decision not to take part will not in any way change your treatment and your consultant will continue to look after you as before.

What are the arrangements for compensation?

This research project has been approved by an independent Research Ethics Committee who believe that it is of minimal risk to you. However, research can carry unforeseen risks and we want you to be informed of your rights in the unlikely event that any harm should occur as a result of taking part in this project. No special compensation arrangements have been made for this project but you have the right to claim damages in a court of law. This will require you to prove a fault on the part of the hospital and/or any manufacturer involved.

Who do I speak to if problems arise?

If you have any complaints about the way in which this research project has been, or is being conducted, please, in the first instance, discuss them with your consultant or Dr Steve Cunningham, the Principal Investigator, at Royal Hospital for Sick Children, Edinburgh on 0131 536 0641. If the problems are not resolved, or you wish to comment in any other way, please contact the Chairman of the Research Ethics Committee, by post via the Research and Development Office, Institute of Child Health, 30 Guilford Street, London, WC1N 1EH, or if urgent, by telephone on 020 7905 2620, and the Committee administration will put you in contact with him.

Thank you for taking the time to read this information sheet.