Patient Information Sheet

1. Study Title EMBARC: THE EUROPEAN BRONCHIECTASIS REGISTRY

2. Invitation Paragraph

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like further information. Take time to decide whether you wish to take part.

3. What is the purpose of the study?

This study is seeking to establish a register of patients diagnosed with bronchiectasis around Europe. We wish to know more about how we treat bronchiectasis and how many patients there are in Europe with this condition. One way of doing this is to record information about patients that are diagnosed with bronchiectasis. As part of this study we will store simple information about you, such as your age, the results of your blood tests and x-rays and the treatments that you have received. This will help us to understand the impact of bronchiectasis on you, and on healthcare in Europe. The users of the database may include doctors, university researchers and companies including the pharmaceutical industry. The registry may require users to pay towards the costs of administering the database but the database is not profit making. You will not personally receive any financial benefit from taking part in the research.

Currently there are very few drugs or treatments that are proven to work for bronchiectasis because very few clinical trials have been performed. The data collected in the registry will help us to evaluate how well treatments work and help to design better clinical trials by understanding more about the disease.

Finally, we want to identify patients who may be willing to take part in clinical trials in the future. If you may be willing to consider participating in the future, we will store your contact details on file. If the opportunity to take part in a trial arises, your doctor may contact you. Participation in any future study or trial will be entirely voluntary and any future study will have the approval of your local research ethics committee or review board. You may ask at any time not to be contacted further.

4. Why have I been chosen?

You are being asked to participate because your doctor has diagnosed you with bronchiectasis.

5. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form, and will be given this information sheet and a copy of the signed consent form to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. Any data about you that we have collected will remain in the database, unless you ask us to delete it.

6. What will happen to me if I take part?
We will record information about your health in a secure computer database which will be held in the University of Dundee. We will record simple information such as your name, age, gender, the results of your blood tests and x-rays, and information of the treatment that you receive. We may also record other electronic data about you collected on General Practice and Hospital computer systems, such as your blood results and details of the treatments you have received. Only your doctor and staff maintaining the registry will have access to your personal data. When the study data is provided to researchers to be analysed, your personal information will be removed, so that you cannot be identified. No results that can identify you personally will be released to the public or published.

If you agree to be contacted for future studies, we will store your telephone number, address and/or e-mail address on file. If an opportunity arises in the future for a clinical study or trial in bronchiectasis that you may be eligible to participate in, your doctor would contact you to ask if you wish further information about the study. You will be under no obligation to take part in this study and any future study would be approved by your **local [research ethics committee] [institutional review board]**. You can ask us at any time not to be contacted further.

7. ***Do I have to agree to all parts of the study?***
No. It is up to you to decide which, if any, of the parts of the study you are willing to participate in. If you are happy for your data to be recorded, but do not wish to be contacted in the future about additional studies simply initial the appropriate boxes on the consent form and leave blank those areas that you do not wish to take part in.

Participation in every aspect of this study is voluntary. You may choose to take part in none, all or some of the components of the study, without your clinical care being affected in any way.

7. What are the possible disadvantages of taking part?
Participating in the study will have no implications for you or your treatment, or for future insurance. All data will be stored securely. We do not anticipate any disadvantages of taking part.

8. What the possible benefits of taking part
There will be no direct clinical benefit to you from taking part in the study. However, the outcome of the research could influence the care of other patients in the future.

9. Will my taking part in this study be kept confidential?
All information that is collected about you during the course of the research will be kept strictly confidential. The result of the study will not be recorded in your medical notes. No data about individual patients will be published or shared with others.

10. What will happen to the data after completion of the study?
Your data will be kept for 10 years after the study has been completed. After this your data will be permanently de-identified. This means that the data will still be stored, but it will be no longer linked to your personal information, and even the researchers will not be able to identify which data refers to you.

11. Complaints
If you have any concerns about your participation in the study you have the right to raise your concern with your doctor involved in conducting the study or a doctor involved in your care. If you have a complaint about your participation in the study, you should first talk to your

doctor involved in the study. However you have the right to raise a formal complaint. You can make a complaint to the Chief Investigator of the study, Dr. James Chalmers, or to the Complaints Officer at your hospital

Complaints and Feedback Team
The Business Unit, Level 7, Laboratory Corridors B and F
Ninewells Hospital
Dundee DD1 9SY
Email: nhstaysidecomplaints@thb.scot.nhs.uk

In the event that you think you have suffered harm as a result of your participation in the study there are no automatic financial compensation arrangements. However, you may have the right to make a claim for compensation against the Sponsor, the University of Dundee. Where you wish to make a claim, you should consider seeking independent legal advice but you may have to pay for your legal costs. The University of Dundee maintains a policy of insurance which provides both legal liability cover and no fault compensation in respect of accidental injury.

12. What will happen to the results of the research study?
The results may be presented at scientific meetings and published in scientific journals. Your name or any other details that may identify you will not be used in any publications.

13. Who has reviewed the study?
The Scotland A Research Ethics Committee which has responsibility for reviewing medical research studies has raised no objections to this study.

14. Who is organising and funding the research?
The study is being sponsored by the University of Dundee and is organised by EMBARC and the European Respiratory Society (ERS), in collaboration with specialists from across Europe. It is funded by a variety of organisations, including the ERS.

15. Contact for Further Information

Chief Investigator: Dr. James Chalmers
Ninewells Hospital & Medical School
University of Dundee, Scotland, UK
jchalmers@dundee.ac.uk

For independent information about the registry or to get advice please contact the European Lung Foundation: info@europeanlung.org

Thank you very much for taking the time to read and consider your participation in this study.