

Written informed consent was obtained from all study participants using the forms below.

## **INFORMATION SHEET – ACHALASIA PATIENTS**

### **Research Study : A case control study of aetiological factors in achalasia**

You are invited to participate in a research study to examine factors that may be involved in a disease of the gullet (oesophagus) known as achalasia. 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. Take time to decide whether or not you wish to take part. Thank you for reading this.

We hope to learn the role of viral infections, autoimmune (a condition where the body's own immune system attacks normal cells) and hereditary (genetic) factors in achalasia. **You were selected as a possible participant for this study as you have a previously attended the Royal Victoria Hospital Gastrointestinal laboratory or the x-ray department to have a test of your swallowing.**

If you decide to participate, it will firstly involve answering some questions about your swallowing and other symptoms, past medical history, family history, medications, previous treatment etc. This may take up to 30 mins to complete. The second part of the study will involve obtaining a blood sample from a vein in your arm. A needle will be inserted in the vein and 30 mls of blood removed. The last part of the study involves taking a mouth swab. A cotton bud will be used to obtain a saliva sample from the mouth. The above can be done at your convenience in your own home or at the Royal Victoria Hospital.

Participation in this study is voluntary. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. We would also like your permission to inform your GP about your involvement in the study and to store your blood sample so that we could look at other factors that may come to light in the future. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Your decision whether to participate or not will not affect the future treatment of your condition.

#### **Risk/ Benefit**

There are minimal risks proposed in this study. Occasionally, taking a blood sample can result in mild discomfort or bruising. Results of this study will increase our knowledge about the causes of achalasia. This information could possibly lead to an improvement in the treatment of patients with achalasia in the future. It is unlikely that you will have any direct benefits from this study.

#### **Confidentiality**

We will keep all information collected during this study solely in order to conduct our study. This data will be held confidentially in a locked cabinet in a locked room.

All information gathered will have no patient identifying details. Any data that may be published in scientific journals will not reveal the identity of the subjects.

If you have any questions about the research, please ask. We can be contacted at the phone no. stated below.

Thank you.

Dr.Brian Johnston  
Consultant Physician  
Royal Victoria Hospital

Dr.Kar Wai Lau (Study Researcher)  
Department of Epidemiology and Public Health  
Queens University of Belfast  
Tel : 07905 928293

### **Research Study : A case control study of aetiological factors in achalasia**

You are invited to participate in a research study to examine factors that may be involved in causing a disease of the gullet (oesophagus) known as achalasia. 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. Take time to decide whether or not you wish to take part. Thank you for reading this.

We hope to learn the role of viral infections, autoimmune (a condition where the body's own immune system attacks normal cells) and hereditary (genetic) factors in achalasia. **You were selected as a possible participant for this study as a healthy volunteer.**

If you decide to participate, it will firstly involve answering some questions about your lifestyle such as smoking and alcohol, medications, etc. This may take up to 30 mins to complete. The second part of the study will involve obtaining a blood sample from a vein in your arm. A needle will be inserted in the vein and 30 mls of blood removed. The last part of the study involves taking a mouth swab. A cotton bud will be used to obtain a saliva sample from the mouth. The above can be done at your convenience in your own home or at the Royal Victoria Hospital.

Participation in this study is voluntary. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. We would also like your permission to inform your GP about your involvement in the study and to store your blood sample so that we could look at other factors that may come to light in the future. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

#### **Risk/ Benefit**

There are minimal risks proposed in this study. Occasionally taking a blood sample can result in mild discomfort or bruising. Results of this study will increase our knowledge about the causes of achalasia. This information could possibly lead to an improvement in the treatment of patients with achalasia in the future. Although there is no direct benefit to you, you are playing a vital role in medical research.

#### **Confidentiality**

We will keep all information collected during this study solely in order to conduct our study. This data will be held confidentially in a locked cabinet in a locked room. All information gathered will have no patient identifying details. Any data that may be published in scientific journals will not reveal the identity of the subjects.

If you have any questions about the research, please ask. We can be contacted at the phone number stated below.

Thank you.

Dr.Brian Johnston  
Consultant Physician  
Royal Victoria Hospital

Dr.Kar Wai Lau (Study Researcher)  
Department of Epidemiology and Public Health  
Queens University of Belfast  
Tel : 07905 928293

## CONSENT FORM

Name of Research : **A case control study of aetiological factors in achalasia**

	Please tick
box	
1. I confirm that I have read and understand the information sheet dated 4/7/2005 Version 1.4 for the above study and I have had the opportunity to ask questions.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
4. I consent to my blood sample being tested for viruses, hereditary (genetic) and autoimmune factors.	
5. I agree to take part in the above study.	

\_\_\_\_\_  
Name of subject

\_\_\_\_\_  
Signature of subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Signature of Researcher

\_\_\_\_\_  
Date

\* 1 for patient; 1 for researcher; 1 to be kept with hospital notes

Signed: Helen Coleman