



UNIVERSITY OF
Southampton

NHS
University Hospital
Southampton
NHS Foundation Trust

W A T C H
Wessex AsThma CoHort of Difficult Asthma

VOLUNTEER CONSENT FORM

Document Version: 4.5, 16 Feb 2018 **Study number:** W_____/_____
Ethics Rec No.: 14/WM/1226
Principal Investigators: Dr Ramesh Kurukulaarachy, Professor Peter Howarth

This form is in three parts. Part A relates to the main WATCH study. Part B relates to the Detailed Biological Characterisation Sub-study. Part C is about storage of samples for genetic studies and data sharing.

Please read all parts. You may consent to Part A, the main study, but not to Part B or C if you wish.

Please initial one of the boxes against each statement, indicating whether you agree/consent or not.

PART A Consent for the main study.

	Agree / Consent?	
	Yes	No
1. I have read the Patient Information Sheet version 4.5, dated 12/10/2017 and this consent form; version 4.5, dated 16/02/2018. All my questions about WATCH and my part in it have been answered and I have had enough time to make my decision. I freely consent to take part in this research study.	<input type="checkbox"/>	<input type="checkbox"/>
2. I understand that taking part is voluntary and that I am free to withdraw at any time without giving any reason, and my medical care and or legal rights will not be affected.	<input type="checkbox"/>	<input type="checkbox"/>
3. I understand that relevant sections of my medical notes, data collected during my clinic visits, plus relevant GP care data from Hampshire Health Record or other comparable GP health record systems will be looked at by researchers from University of Southampton and from the UHS NHS Trust and included in the data for this research study. I give permission for these researchers to have access to my records.	<input type="checkbox"/>	<input type="checkbox"/>
4. I agree for blood and urine samples to be taken and for samples to be taken from the inside of my mouth and nose. I understand how the samples will be collected, that giving samples for this research is voluntary and that I am free to withdraw my agreement to use of the samples at any time, and my medical care and legal rights will not be affected.	<input type="checkbox"/>	<input type="checkbox"/>
5. When my doctor, or clinician, believes it will be helpful to my care I understand that they may ask for sputum (phlegm) samples. I agree that, after this any remaining amounts of these samples may be stored and used for research.	<input type="checkbox"/>	<input type="checkbox"/>
6. When my doctor, or clinician, believes it will be helpful to my care I understand that they may ask for a bronchoscopy. I agree that, after this any remaining amounts of these samples may be stored and used for research.	<input type="checkbox"/>	<input type="checkbox"/>

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Agree / Consent?

Yes No

- | | | |
|---|--------------------------|--------------------------|
| 7. I understand that samples obtained from this study may be passed to researchers at other academic institutions (hospitals and universities) if they are able to carry out analyses that will help research studies into asthma. I agree that samples collected during this study may be passed to other researchers. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. I understand that samples obtained from this study may be passed to commercial companies (pharmaceutical companies) if they are able to carry out analyses that will help research studies into asthma. I agree that samples collected during this study may be passed to such collaborators. | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. I understand and agree that the information collected about me in this study may be shared anonymously with other researchers to support other ethically approved asthma research in the future. I understand that these researchers may be in countries within or outside the European Economic Area (EEA), and that some of these countries outside the EEA do not have laws regulating the transfer of personal data. I give my permission for such transfer of data. | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. I agree to my GP being informed of my participation in the study. I have informed you about my participation in any other research study. | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. I understand I shall not benefit financially if this research leads to the development of a new treatment or test. | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. I understand I may be contacted in future to discuss possible participation in other local research studies. | <input type="checkbox"/> | <input type="checkbox"/> |

Name of Patient

Date

Signature

Name of person taking consent

Date

Signature

One copy for patient, one for researcher, one to be kept with hospital notes.

PART B Consent for Additional Biological Samples

	Agree / Consent?	
	Yes	No
13. I have read the "Detailed Biological Characterisation" Patient Information Sheet version 1.0, dated 16/02/2018 and this consent form; version 4.5, dated 16/02/2018. All my questions about this WATCH sub study and my part in it have been answered and I have had enough time to make my decision. I freely consent to take part in this research study.	<input type="checkbox"/>	<input type="checkbox"/>
14. I agree for Exhaled Breath samples to be taken. I understand how the samples will be collected, that giving samples for this research is voluntary and that I am free to withdraw my agreement to use of the samples at any time, and my medical care and legal rights will not be affected.	<input type="checkbox"/>	<input type="checkbox"/>
15. I agree for Induced Sputum samples to be taken. I understand how the samples will be collected, that giving samples for this research is voluntary and that I am free to withdraw my agreement to use of the samples at any time, and my medical care and legal rights will not be affected.	<input type="checkbox"/>	<input type="checkbox"/>
16. I agree for Nasal Lavage samples to be taken. I understand how the samples will be collected, that giving samples for this research is voluntary and that I am free to withdraw my agreement to use of the samples at any time, and my medical care and legal rights will not be affected.	<input type="checkbox"/>	<input type="checkbox"/>
17. I agree for Nasal Brushing samples to be taken. I understand how the samples will be collected, that giving samples for this research is voluntary and that I am free to withdraw my agreement to use of the samples at any time, and my medical care and legal rights will not be affected.	<input type="checkbox"/>	<input type="checkbox"/>
18. I agree for Bronchoscopy samples to be taken. I understand how the samples will be collected, that giving samples for this research is voluntary and that I am free to withdraw my agreement to use of the samples at any time, and my medical care and legal rights will not be affected. I understand that undertaking this procedure will require a separate consent form, as required by UHS NHS Trust, at the time of the procedure.	<input type="checkbox"/>	<input type="checkbox"/>

Name of Patient_____
Date_____
Signature_____
Name of person taking consent_____
Date_____
Signature*One copy for patient, one for researcher, one to be kept with hospital notes.*

Part C Consent for storage of samples and participation in genetic studies/ genomic data sharing

We would also like to undertake some genetic analyses on the samples you have provided and to store any samples collected for future research in asthma. Genomic studies examine genetic differences across the human genome (set of human genes). Researchers study the association between genes and health conditions or personal characteristics like vision, obesity, or behavioral traits. In this part of the study we will be collecting information about your individual genes. We will use this information for our study objectives. In addition, if you agree, the data will be entered into external scientific databases so that it can be broadly shared with other researchers performing other genomic studies. For example, the National Institutes of Health (NIH, an agency of the US federal government) maintains a database called "dbGaP." Databases like this serve as a repository of all kinds of genomic data from studies funded by the NIH and conducted in the US and around the world. The aim of collecting this information in a repository is to allow qualified researchers to look for genetic connections for a range of topics in the future. The information may be used to learn if certain genes are associated with certain traits, diseases and /or treatment effects. Making data broadly available in this way means that your contribution and the data generated in this study could be helpful in advancing other areas of scientific research.

Traditionally used identifying information about you (such as name, phone number, address) will NOT be included in these databases or shared with others. De-identified genomic data generated in this study may be deposited in databases that will be publicly accessible via the Internet. Researchers with an approved study may access and utilize your de-identified genetic, genomic and/or health information deposited in the database (dbGAP) after approval by the regulatory authority (NIH). Strict safety measures are in place to protect the privacy of your information. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you or your family. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and keep your information confidential.

You may withdraw consent for research use of genomic data or health information at any time. In this event, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be retrieved.

If you decide not to participate in this part of the study it will not affect your involvement in the main part of the study. This form is designed to allow you to state your preference for this extra participation.

PLEASE TURN OVER

WATCH Volunteer Consent Form

Please initial boxes if you agree with each statement.

Agree / Consent?
Yes No

1. Blood (and if taken, sputum or buccal (cheek) swab) samples taken during the study will be extracted for DNA or RNA which will then be used in genetic analyses to help further our understanding of how asthma develops and what determines response to treatment or disease severity. We plan to conduct scans across all parts of your DNA and RNA to help identify new genes that may influence asthma expression and to test hypotheses of how genes influence treatment of asthma.

The information collected in these studies is unlikely to have any individual significance and there are no plans to communicate any findings from genetic studies to participants. If you would prefer not to take part in any genetic analyses as part of this study, this will in no way bar you from the main part of the study. Please let us know whether you would like to take part in the genetics part of this study by initialling the box below.

I agree to take part in the genetic analysis part of this study

☐ ☐

2. If you do not wish your data to be shared as described above, you may still take part in this study and your data will not be submitted to an external database. Please indicate below by initialling the appropriate box below whether you consent to the sharing of your data in this way.

I consent to my genetic, genomic and/or health information being submitted to an external database and broadly shared with other researchers

☐ ☐

3. If there are any unused samples remaining after completion of the study, these may be saved for future asthma related research. Please initial the box below if you are happy with this.

I agree to have any unused sample(s) to be stored and used for future asthma-related research.

☐ ☐

Name of Patient

Date

Signature

Name of person taking consent

Date

Signature

One copy for patient, one for researcher, one to be kept with hospital notes.