

Centre:**Study number: 09/H0504/75****Study ID number:**

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CONSENT FORM**Autoinflation Randomised Study in school age children (4-11 years) with glue ear (AIRS).**

(Version 3, 23-02-11)

Name of Chief Investigator: Dr Ian Williamson**Please initial box**

1. I confirm that I have had the study explained to me by the research nurse, and had the chance to read the parent information sheet (Version 4, dated 23-02-11) and either the 4-5 year old (Version 2, dated 25-06-2009) or the 6-11 year old patient information sheet (version 3, dated 05-08-2009) and ask questions that have been answered satisfactorily.
2. I understand that all my child's details will be kept confidential and their name will not appear on any reports or documents.
3. I understand that taking part in the study will involve further trips for me and my child to the surgery.
4. I am happy for my child to have their ears checked immediately after using the balloon with an extra tympanogram.
5. I understand that if my child participates in the randomised part of the study and is randomised to use the autoinflation treatment, I will need to make sure they perform the treatment as instructed, and that the total length of treatment is up to three months.
6. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the research team, from regulatory authorities or from an NHS Trust where it is relevant to my child taking part in this research. I give permission for these people to have access to my child's records.
7. I understand that our participation is voluntary and that we are free to withdraw at any stage without giving reasons and without my or my children's medical care or legal rights being affected.
8. I agree to my GP being informed of my child's participation in the study.
9. I agree to my child taking part in this study.

Name of Parent

Signature

Date

Name of research nurse

Signature

Date

White copy: GP practice, Yellow copy: Southampton University, Green copy: Patient

Primary Medical Care

University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST, United Kingdom

Tel: Fax:

Centre:

Study number: 09/H0504/75

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**To be completed
by the child and
their**

ASSENT FORM

Autoinflation Randomised Study in school age children (4-11 years) with glue ear (AIRS).
(Version 2, 25/06/2009)

Have you read (or had read to you) about this study?	Yes/No
Has somebody else explained this study to you?	Yes/No
Do you understand what this study is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Have you had your questions answered in a way you understand?	Yes/No
Do you understand it's OK to stop taking part at any time?	Yes/No
Are you happy to take part?	Yes/No

If any answers are 'no' or you don't want to take part, you don't need to

If you do want to take part, you can write your name below

.....
Your name

.....
Date

The nurse who explained this study to you needs to sign too:

.....
Name of research nurse

.....
Date

Thank you for your help

White copy: GP practice, Yellow copy: Southampton University, Green copy: Patient

Primary Medical Care

University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST, United Kingdom

Tel: [REDACTED] Fax: [REDACTED]