



Centre number

Study number MREC 03/11/073

Patient ID number

CONSENT FORM

A double-blind randomized placebo-controlled trial of topical intranasal steroids in 4- to 11-year-old children with otitis media with effusion (OME) in primary care

Please initial box

1. I confirm that I have had the study explained to me by the nurse, and had the chance to read the information sheet dated (Version 6, dated 12/7/05, Child's Version 3, dated 26/1/04) and ask questions.

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 understand that if my child participates in the next part of the study I will need to administer the study nasal spray as instructed once a day, and that the total length of treatment is 3 months.

5. I understand that if my child participates in the next part of the study the practice research nurse will need to check my child's medical notes for 12 months before starting the spray and for 9 months thereafter for consultations relating to their ear problems and provide this information to the researchers. I give permission for her to do this.

6. I understand that our participation is voluntary and that we are free to withdraw at any stage without my or my children's medical care or legal rights being affected.

7. I agree to my child participating in this study.

Name of child _____ Date _____ Signature _____

Name of parent / guardian _____ Date _____ Signature _____

Name of nurse _____ Date _____ Signature _____

3 copies (co-ordinator/patient/practice)