University of BRISTOL | University of Southampton | Bristol Randomised Trials Collaboration | REST the runny ear study

IRAS ID: 229293

Funded by NHS National Institute for Health Research

Participant ID:

The Runny Ear Study is funded by the National Institute for Health Research's HTA Programme HTA 16/85/01

# CONSENT TO TAKE PART IN THE RUNNY EAR STUDY

**I understand and agree: (Points 1-7 must be initialled by the parent for the child to be included in the study)**

**INITIAL boxes**

1. I have read the Parent Information Sheet (v2.0, date: 10/05/2018) for the Runny Ear Study and have had any questions answered satisfactorily. ☐
2. My child's participation is voluntary and he/she can stop taking part at any time without giving any reason and without his/her medical care or legal rights being affected. ☐
3. My child will be given one of 3 treatments - antibiotic ear drops, "just in case" or "delayed" oral antibiotics or immediate oral antibiotics; I am willing to give the allocated medicine to my child as advised by my child's doctor/nurse. ☐
4. I am willing to complete my child's symptom and recovery questionnaire (online or on paper ) for 14 days and receive regular telephone calls from the study Research Nurse. ☐
5. I am willing to complete a questionnaire 3 months after study entry (online or on paper) about my child's health. ☐
6. That my child's medical records and data collected during the study, may be looked at by NHS-authorised researchers, from regulatory authorities or from the NHS Trust, as relevant to this research. I give permission for these persons to access my child's records. ☐
7. That my child can take part in the above study. ☐

**The following points (8-12) are optional:**

8. I am willing to collect a stool sample from my child on day 14 and 3 months after study entry. ☐
9. I am willing for my child's stool sample to be retained for future research in microbial infections. ☐
10. I am willing to be invited to take part in a telephone interview about my views on the treatment of children's ear infections with no commitment to take part. ☐
11. That the information collected about my child may be used to support other research in the future, and may be shared anonymously with other researchers. ☐
12. **(For children recruited at OOH and WIC sites only)** That our GP can be informed that myself and my child are taking part in this study. ☐

**Child's Name (please print):**

**Parent's Name (please print):**

**Parent's signature:**

**Date:** D D / M M / Y Y Y Y

**Consenting Clinician's Name (please print):**

**Clinician's signature:**

**Date:** D D / M M / Y Y Y Y

**Paperwork management instructions:** Complete one copy.

- Send to Bristol Trial Centre via secure fax **(0117 928 7341)** or encrypted email **(bnssg.rest@nhs.net)** **TODAY.**
- Photocopy and give copy to parent (put it in the shopping bag provided in the Participant Pack).
- Scan into child's medical record and store in the REST Site File (these will be collected at the end of the study).