NHS National Institute for Health Research **WAIT**

T -2 ASSESSMENT & RANDOMISATION CRF (Copy 1 – Trial Manager, Copy 2 – Local Site File)

Serial number: I__I__I__I__I__I Site: I__I__I (e.g LO, AB, LE)

Researcher Initials:I__I__I Date of THIS Visit: I__I__/__I__/__I__I

CONSENT TO USE DATA:	Yes ☐	No ☐	**If NO – DO NOT COMPLETE**

INCLUSION CRITERIA

Age between 10 months and 5 years:	Yes ☐	No ☐
Doctor-diagnosed wheeze, EVER:	Yes ☐	No ☐
Wheeze in the preceding three months:	Yes ☐	No ☐
At least two episodes of wheeze, EVER:	Yes ☐	No ☐
Parent contactable by phone:	Yes ☐	No ☐

EXCLUSION CRITERIA

Regular Montelukast	Yes ☐	No ☐
History of neonatal chronic lung disease	Yes ☐	No ☐
In a drug trial in the preceding three months	Yes ☐	No ☐
Clinician-diagnosed chronic respiratory illness Including structural airway anomaly and CF:	Yes ☐	No ☐
Any other chronic illness predisposing to respiratory infection (including developmental delay with feeding difficulty):	Yes ☐	No ☐

If you have ticked any GREYED-OUT boxes do not register this child for the WAIT study

INFORMED CONSENT TO ENTER STUDY:

Parent and child information sheets reviewed:	Yes ☐	No ☐
Informed consent form signed:	Yes ☐	No* ☐

*If no, please state the reason:

Did not want to take part in a genetic study: ☐
Concerned about confidentiality: ☐
Other (please specify): ☐ _____

If informed consent is NOT given do not collect samples, but please collect demographic data on page 2. If informed consent IS given collect samples as per guidance and also complete administration section on page 3

STUDY VISIT CONDUCTED BY:

Researcher Signature:_____ Print Name:_____ I__I__/__I__/__I__I

I have reviewed all data in this CRF and verify that the contents are consistent with observations and source records.

PI Signature_____ Print Name:_____ I__I__/__I__/__I__I

NHS National Institute for Health Research **WAIT** mcrn PCRN Primary Care Research Network

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Researcher Initials:I__I__I Date of THIS Visit: I__I__/__I__/__I__I

Weight:	I__I__I.I__Ikg	Height:	I__I__I__I.I__Icm	DOB:	I__I__/__I__/__I__I	Sex	M ☐ F ☐

Risk factors

Birth, Atopy and Family History	Yes	No
Preterm Birth < 37wk gestation	☐	☐
Birth weight < 2500g	☐	☐
Allergy:		
Food	☐	☐
Drug	☐	☐
Itchy rash for > 6 months, ever	☐	☐
Eczema, ever	☐	☐
Tobacco Exposure:		
In utero	☐	☐
In household[+]	☐	☐
([+]any household smoking contact)		
Daycare attendance	☐	☐
Immunisation Status:		
Pneumococcus	☐	☐
Influenza	☐	☐
History of Asthma		
Mother:	☐	☐
Father:	☐	☐

Pre-study Illness and Therapy		
Age at 1st wheeze episode	I__Iy I__I__Im	
	Yes	**No**
Wheezes only with viral URTI (episodic)	☐	☐
Wheezes at other times (multitrigger)	☐	☐
Interval between onset of URTI and wheezing:	I__I__I hr	
Admitted to hospital for wheeze:		
In last year?	☐	☐
Ever?	☐	☐
No of courses of systemic steroids in last year	I__I__I	
No of unscheduled medical attendances for wheeze in last year?	I__I__I	
Preventer therapy:		
None	☐	☐
Antileukotriene agents	☐	☐
Maintenance Inhaled Steroids	☐	☐
Episodic inhaled Steroids	☐	☐

Ethnicity

Asian or Asian British	**Mixed**	**Black or Black British**	**White**	**Other Ethnic Group**
☐ Bangladeshi	☐ White & Asian	☐ African	☐ British	☐ Chinese
☐ Indian	☐ White & Black African	☐ Caribbean	☐ Irish	☐ Any other ethnic group
☐ Pakistani	☐ White & Black Caribbean	☐ Any other Black background	☐ White other	☐ I do not wish to disclose my ethnic origin
☐ Any other Asian background	☐ Mixed other			

Saliva sample collected:	Yes ☐	No ☐	Date collected:	I__I__/__I__/__I__I
Saliva sample posted to laboratory:	Yes ☐	No ☐	Date sent:	I__I__/__I__/__I__I
Urine sample collected:	Yes ☐	No ☐	Date collected:	I__I__/__I__/__I__I

STUDY VISIT CONDUCTED BY:

Researcher Signature:_____ Print Name:_____ I__I__/__I__/__I__I

I have reviewed all data in this CRF and verify that the contents are consistent with observations and source records.

PI Signature_____ Print Name:_____ I__I__/__I__/__I__I

Data Entry Use Only: Date Received (DD/MM/YY): __/__/__ Entered (DD/MM/YY):__/__/__ Initials:_____

Monitoring Use Only: Database Cross-checked (DD/MM/YY):__/__/__ Initials: _____

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Serial number: I__I__I__I__I__I Site: I__I__I (e.g LO, AB, LE)

Patient Initials: I__I__I__I Researcher Initials:I__I__I Date of THIS Visit: I__I__/__I__/__I__I

ADMINISTRATION (ONLY COMPLETE IF RECRUITED TO STUDY) – Do not send this page to trial coordinator

Full Name: I_____I

House/flat number: I_____I

Address 1: I_____I

Address 2: I_____I

Address 3: I_____I

Postcode: I__I__I__I__I I__I__I__I

Mobile: I__I__I__I__I__I__I__I__I__I__I__I__I

Landline: I__I__I__I__I__I__I__I__I__I__I__I__I

Email: I_____I

T0 visit booked?: Yes ☐ No ☐ Date: I__I__/__I__/__I__I

Inhaler technique assessed: Yes ☐ No ☐

Further advice/training provided as necessary: Yes ☐ No ☐

STUDY VISIT CONDUCTED BY:

Researcher Signature:_____ Print Name:_____ I__I__/__I__/__I__I

I have reviewed all data in this CRF and verify that the contents are consistent with observations and source records.

PI Signature_____ Print Name:_____ I__I__/__I__/__I__I

Please scan and forward pages 1-2 only to Trial coordinator via secure email on cnwokoro@nhs.net as soon as possible after T-2 visit. Keep this page in local site file with consent forms.

National Institute for Health Research WAIT mcrn PCRN Primary Care Research Network

T-2 VISIT RESEARCHER AIDE-MEMOIRE

BEFORE THE VISIT

- Ensure that you have access to:
  - a stadiometer and scales
  - universal containers and urine collection apparatus
  - Ice box and ice
  - a genotek kit
  - specimen label sheets
  - T-2 proforma
  - Consent form
  - Information sheets
- Ensure that appropriate **language arrangements** are in place if English is not the parents' first language.

DURING THE VISIT

CRF and consent

- Check that parents understand what you are saying, review information sheet and seek informed consent
- If informed consent is not granted then seek consent to use data short of administrative section
- Complete CRF up to the administrative section FOR ALL children (including weight and height), even if they do not agree to take part if consent is provided.
- Leave one copy of consent form with parents.
- Sign and gain PI countersignature on each page that is completed

Specimens – if informed consent gained

- Review sample collection guide
- Collect urine, decant into 2 x 1ml aliquots label with serial number and put on ice immediately.
- Finally collect and label DNA sample with serial number

Administration – if informed consent gained

- Complete the administration section on page 3 of the CRF including:
  - Administrative data
  - Checking and correcting Inhaler technique as necessary
  - Arranging T0 medicines dispensing visit
  - Signing off on CRF
  - Copy consent form and give a copy to parents

AFTER THE VISIT

CRF and consent

- Researcher completing to ensure their sign off is complete (*N.B.* researcher signing form must be delegated on the site delegation log to take consent/complete CRFs).
- CRF pages 1-2 to be **countersigned by local PI**, scanned and secure emailed via [redacted] to [redacted] in London as soon as possible **(any delay will delay stratum allocation).**
- Remember to keep one copy of consent form for local site file (consent and CRF) and give one copy to parents (consent form only).
- London Lab will allocate stratum to complete CRF T-2.

Specimens

- DNA sample to be posted **urgently** with request form in the pre-addressed envelope provided. An electronic copy of the request form must be sent to the trial coordinator on [redacted]
- Urine sample to be taken urgently on ice to be taken to local freezer and frozen at -70 or below for batch courier to London lab.

Stratification and Randomisation

- Trial laboratory technician should analyse DNA samples and complete stratification and inform researcher.
- PI should complete prescription with stratum based on above.
- Research nurse should deliver prescription to local pharmacy
- Local Pharmacist to complete prescription form, allocate IMP number and dispense trial drug for collection by local researcher
- Local researcher should convey IMP to parent.