

REST Baseline Data

Acute Clinical Data

1. How many days has the child had ear discharge before **today**? (Please enter days in box - 7 days max).
2. How unwell do you consider this child to be? (0 = not at all unwell, to 10 = extremely unwell).
3. Temperature in degree Celsius (Range 34.0 - 42.0).
4. Ear Examination:
 - 4.a) Is discharge visible in the affected ear?
 - 4.b) Is a perforation visible in the affected ear?

Yes ☐ No ☐

Yes ☐ No ☐

Child's Medical History

1. Is there a history of acute otitis media (AOM)?
If no, go to Question 2
 - 1.i) If yes, how many episodes **in the last 12 months**? (enter number - **if none, enter 00**).
2. Is there a history of acute otitis media with discharge (AOMd)?
If no, go to Question 3
 - 2.i) If yes, how many ear discharge episodes **in the last 12 months** (those without grommets insitu and not including the current episode)? (enter number - **if none, enter 00**)
3. Is there a history of glue ear?

Yes ☐ No ☐

Yes ☐ No ☐

Yes ☐ No ☐

Submit

Reset

Consent Form

Send the completed consent form to the REST Bristol Study Centre on secure fax:
or via encrypted email: bnssg.rest@nhs.net on the day of recruitment.

Has the parent/legal guardian/patient received written and oral information
about the aim and the content of the study?

REST Study Consent Form

Yes ☐ No ☐

Has the parent/legal guardian/patient given written, informed consent,
using the REST study consent form to participate in the study?

Yes ☐ No ☐

Please confirm child's date of birth for randomisation:

Child's date of birth

dd / mm / yyyy

Submit

Reset

Child/Parent Contact Details

Send to the REST Bristol Study Centre on secure fax: or
via encrypted email: bnssg.rest@nhs.net on the day of recruitment.

1. GCP checks - Has the child's parent/legal guardian read and completed the REST study consent form?

Yes ☐ No ☐

NB: If the consent form is not completed, do not continue

2. GCP checks - If the child is old enough (Age 6 to <16) to understand their role in the study, has he/she read and completed the study assent form?

--Choose an option--

3. GCP checks - If the child is old enough to understand their role in the study but the assent form has **not** been completed, please provide a brief justification.

4. Child's NHS number

5. Child's name = First name(s)

6. Child's name = Surname

7. Child's date of birth

dd / mm / yyyy

8. Child's gender

Female ☐ Male ☐

9. Child's registered GP practice

10. Parent/guardian's name = First name(s)

11. Parent/guardian's name = Surname

12.i) Parent/guardian's address

12.ii) Parent/guardian's postcode

13. Parent/guardian preferred contact telephone number (Main/Mobile)

14.i) Parent/guardian preferred contact telephone number (Secondary)

14.ii) Parent/guardian preferred contact telephone number (Secondary). Select type of contact:

--Choose an option--

15. Parent/guardian email address

16. Parent's preferred weekday contact times (please tick all that apply)

16.i) Morning 9 - 12

Yes ☐

16.ii) Afternoon 12-5

Yes ☐

16.iii) Working day 9-5

Yes ☐

16.iv) Evening 5-8

Yes ☐

16.v) Anytime 9-8

Yes ☐

17. Symptom Questionnaire preferred option

App ☐ Paper ☐

18. Symptom Questionnaire daily reminders

Yes ☐ No ☐

19. Preferred Symptom Questionnaire daily reminder method

Email ☐ Text ☐

Submit

Print

Reset

Decliner Parent Interview Form

1. Has the child (if age 6+), the parent/legal guardian or the clinician declined participation in the study?

Yes ☐ No ☐

2.i. If child is non-eligible or participation is declined, can **anonymized** information on reasons for exclusion be used by the study team?

Yes ☐ No ☐

2.ii. If yes, select a reason for declining:

--Choose an option--

If child or parent/legal guardian declines, please invite the parent to take part in a decliner interview and follow the link below

[Decliner parent interview form](#)

Submit

Reset

Eligibility Confirmation (ELS)

Inclusion criteria (All must be ticked "Yes" for child to be eligible)

1. Parent/legal guardian is available in person to give consent? Yes ☐ No ☐
2. Parent/legal guardian willing for child to be assessed for eligibility? Yes ☐ No ☐
3. Child aged between ≥ 12 months and < 16 years? Yes ☐ No ☐
4. Child has had recent onset (≤ 7 days) unilateral AOM with recent onset (≤ 7 days) currently visible otorrhoea (or seen by parent in the previous 24hrs)? Yes ☐ No ☐
5. Parent/legal guardian willing and able to administer ear drops? Yes ☐ No ☐
6. Parent/legal guardian willing, able and available to complete Symptom Questionnaire and receive telephone calls from research team for up to 14 days or until symptoms resolved for 2 days running? Yes ☐ No ☐

Exclusion criteria (All must be ticked "No" for child to be eligible)

1. Symptoms/signs suggestive of bilateral AOM/AOMd? Yes ☐ No ☐
2. Has symptoms/signs suggestive of serious illness and/or complications, e.g. mastoiditis, and/or requires immediate hospitalisation? Yes ☐ No ☐
3. Requires immediate oral antibiotics, e.g. for another infection or severe AOMd? Yes ☐ No ☐
4. At risk of serious complications?
If yes, please specify:
4.i) Significant immunosuppression? Yes ☐ No ☐
- 4.ii) Significant heart, lung, renal, liver or neuromuscular disease? Yes ☐ No ☐
- 4.iii) Cystic fibrosis? Yes ☐ No ☐
- 4.iv) Trisomy 21 (Down's syndrome)? Yes ☐ No ☐

Yes ☐ No ☐

4.v) Significant craniofacial malformation, e.g. significant cleft palate?

Yes ☐ No ☐

5. Has grommet(s) in situ in AOMd ear?

Yes ☐ No ☐

6. Is currently taking oral or topical (in affected ear) antibiotics?

Yes ☐ No ☐

7. Allergy to ciprofloxacin?

Yes ☐ No ☐

8. Allergy to penicillin/anaphylaxis to another beta-lactam agent **and**
allergy to clarithromycin?

Yes ☐ No ☐

9. Has already participated in this trial?

Yes ☐ No ☐

10. Has taken part in any research involving medicines within last 90 days?

Yes ☐ No ☐

Outcome of eligibility criteria

1. Is child eligible and the parent/legal guardian (and child if age 6+) willing
to consider trial entry?

Yes ☐ No ☐

If the child (if age 6+), the parent/legal guardian or the clinician answered
"No" to this question, please **go to the Decliner Parent Interview form**

Submit

Reset

Pre-eligibility Screening Form

REST Study Pre-eligibility screening (If marked "Yes" to all questions, then proceed to Eligibility Screening form).

1. Have you completed the Study Specific GCP & Informed Consent slides? Yes ☐ No ☐
2. Does the child have ear discharge (seen by parents/legal guardians or clinician in the last 24 hours)? Yes ☐ No ☐
3. Is parent/legal guardian available to give consent in person? Yes ☐ No ☐
4. Is parent/legal guardian willing to consider trial entry? Yes ☐ No ☐

If the child (if age 6+), the parent/legal guardian or the clinician answered "No" to Question 2 or Question 3 or Question 4, please **go to the Decliner Parent Interview form**

REST study information sheets

If "Yes" to all answers please print the relevant information sheet

[Parent/Legal guardian Summary Information Sheet](#)

[Child Information Sheet \(Age 6-10\)](#)

[Child Information Sheet \(Age 11-16\)](#)

Submit

Reset

Randomisation Outcome Form.

The outcome of the randomisation is:

--Choose an option--

[Immediate Ciprofloxacin drops
advice sheet](#)

[Delayed Oral Antibiotics advice
sheet](#)

[Immediate Oral Antibiotics advice
sheet](#)

Select and print the correct advice sheet, issue the prescription and give
parents the patient pack. Thank you

Submit

STANDARD OPERATING PROCEDURE FOR:

Obtaining Informed Consent and Assent from Parents and Children for the Runny Ear Study (REST)

SOP Details:

Number: SOP-REST-XXXX	Version: 1.0
Author(s): Sue Harris Title: REST Research Nurse	Date: 23/01/2019
Authorised by: Rachel Davies Title: Acting Co-Head of Research Governance and Research and Human Tissue Manager/Study Sponsor	Date: 24/01/2019
Date operational:	
Date to be reviewed:	

Review History:

Review Date:		Reviewed By:	
Review amendments:			
Amended date:		Amended by:	
Authorised date:		Authorised by:	

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Review amendments:			
Amended date:		Amended by:	
Authorised date:		Authorised by:	

Review Date:		Reviewed By:	
Review amendments:			
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Authorised date:		Authorised by:	

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1 Document History

Revision	Date	Author	Changes
0.1	01/10/2018	Sue Harris	None, this is the first draft
0.2	23/01/2019	Sue Harris	Amendments/deletions to text following review by sponsor

2 Background

Following strict Good Clinical Practice (GCP) guidelines, no research activity or recruitment can be undertaken on a study participant without their written and verbal informed consent (and assent, where applicable). It is the responsibility of all study team members or primary care recruiting staff, to explain clearly all study interventions and assessments, to ascertain the participants' understanding and knowledge of those interventions and assessments and to obtain their consent (and assent, where applicable), to proceed with the interventions and assessments.

3 Purpose

This document provides guidelines for taking informed consent and assent for children deemed eligible to participate in the REST study.

These guidelines are for use by all members of research and administrative staff working on the study, to ensure that:

- Parents/legal guardians and children are giving valid informed consent and assent to take part in REST;
- Consent and assent forms are completed correctly;
- The informed consent process complies with ICH-GCP standards based on the Declaration of Helsinki (1996) and as set out in the Medicines for Human Use (Clinical Trial) Regulations 2004 (as amended in 2006 and any subsequent amendments), EU Directive 2001/20 EC and the Research Governance Framework for Health and Social Care.

4 Scope

This SOP applies solely to obtaining informed consent from the parents/legal guardians of the children recruited to the REST study and, where applicable, the assent of the participant children, and should not be used for any other study.

REST is an opportunistic study of an acute condition, in which it will not be possible to wait 24 hours to request consent, since the primary outcome requires that the child is prescribed two alternatives to oral antibiotics at the recruitment interview, on the day they present with ear discharge.

Approval has been given by the NHS Research Ethics Committee: South Central - Oxford B; for the child's eligibility to be assessed based on verbal agreement from the parent, prior to informed consent.

5 Definitions & Abbreviations

5.1. Definitions

What is consent?

Consent is defined as 'the voluntary agreement of an adult or competent child, based on adequate knowledge and understanding of relevant information, to participate in research' (MRC 2004) and is the foundation of any ethical research.

For people to have the capacity to make an informed choice, they must be able to:

- Comprehend and retain information material to the decision, especially the consequences of having or not having any intervention.
- Use and weigh this information in a decision-making process.
- Reach and communicate a decision.

Consenting for children

The Clinical Trials Regulations (Medicines for Human Use (Clinical Trial) Regulations 2004 (as amended in 2006 and any subsequent amendments) define a minor as someone under the age of 16 years. The regulations specify that for a minor to participate in a clinical trial, a person with parental responsibility must give informed consent. It is considered good

practice to gain the child's assent and agreement to take part in the clinical trial regardless of age. The extent to which this must (and can) be done will depend on a child's ability to both understand the situation and express their opinion (it is recognised that the child's capacity for either may vary).

For school-age children (approximately 6 years old but may be younger or older depending on cognitive development and the effect of the child's illness or pain on their ability to process information), it is of **major importance** to inform the child and seek assent.

The decision as to whether a child should give assent lies with the parent/legal guardian and clinician. The expectation from the study sponsor is that an individual assessment will be made for each child, and that for all children over 6 years old an assent form will be completed, or justification provided as to why not.

For any child, objections raised by the child at any time during the study should be considered, and the child's will, respected.

The REST recruiter may use the following information as guidance in seeking parental consent and assessment of competence of the child for assent.

Parental responsibility (England and Wales)

- Mothers automatically have parental responsibility regardless of marital status
- Parents married to each other at the time of birth, or if they have jointly adopted a child, will both have parental responsibility and will not lose it if divorced
- Unmarried fathers do not automatically have parental responsibility but can acquire it via the following routes:
 - By jointly registering the birth of the child with the mother (for children born after 1st December 2003). If a child was registered before 1st December 2003 and the father was not named on the birth certificate, the child can be re-registered to include the father's name.
 - Making a parental responsibility agreement with the mother
 - Obtaining a parental responsibility order, made by a court (www.direct.gov.uk)

5.2. Abbreviations

ANP	Advanced Nurse Practitioner/Prescriber
CI	Chief Investigator
CIS	Child Information Sheet
GCP	Good Clinical Practice
GLP	Green Light Process
GP	General Practitioner
PI	Principal Investigator
PIS	Parent Information Sheet
SP	Study participant
UHB	University Hospitals Bristol NHS Foundation Trust
UoB	University of Bristol

6 Pre-Requisites

6.1 *Pre-Requisite Knowledge & Training*

- GCP training (if primary care staff already certified); **or**
- REST study informed consent training (for those primary care staff not GCP-certified).
- REST study TRANSFoRm electronic data platform training for all primary care recruiting staff

6.2 *Pre-Requisite Equipment & Systems*

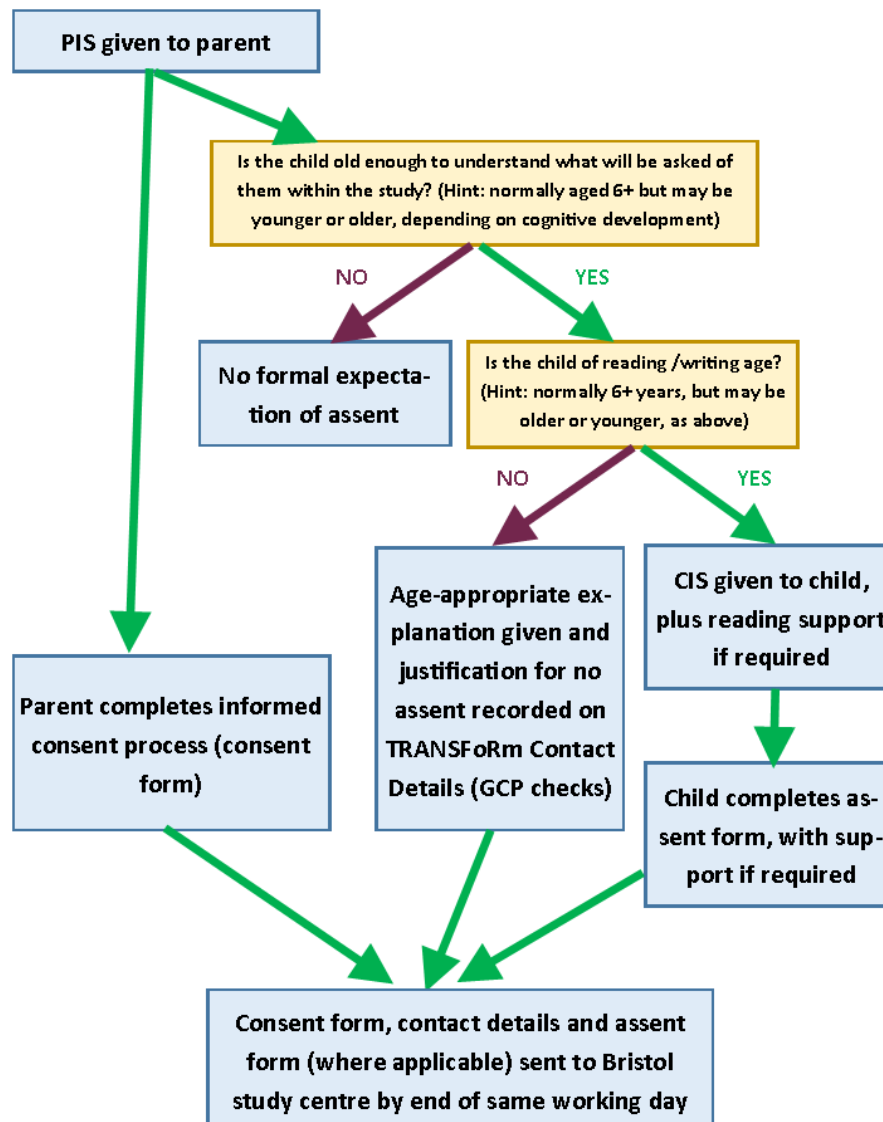
- REST study TRANSFoRm electronic data capture and entry platform.

7 Roles & Responsibilities

Who	What & Why
Principal Investigator	Ensures that this SOP is adhered to in all local sites. Delegates certain activities to local researchers; all delegated activities documented on the trial Delegation Log.
Primary care site staff	Trained to obtain informed consent and assent from study parents/legal guardians and children; adherence to content of this SOP in all recruitment activity.
Study research nurse	Updates this SOP and adheres to content in all study operations.
Study administrator	Adherence to content of this SOP in all study operations.
Study manager	Ensures adherence to content of this SOP in all study operations.
Study sponsor (UoB)	Reviews and authorises this SOP.
UHBristol Research & Innovation team	Monitors site adherence within the monitoring plan.

8 Procedure

8.1 Procedure Diagram



8.2 Procedure Narrative

The stages of the consenting process are described below.

Prior to the start of recruitment at the site

Sponsor approval for recruitment at the site requires the primary care site staff who will be taking consent be appropriately qualified, experienced, trained in the study and GCP/or informed consent, be listed on the study delegation log and signed as competent by the PI.

Provision of study information to parents/legal guardians of potentially eligible children prior to consent

The study poster and PIS will be provided to be displayed and available in practices' waiting rooms.

Where possible, receptionists will be asked to inform parents the practice is taking part in the study and ask if they are interested in further information. If a parent agrees, the receptionist will give them the PIS to read while waiting.

For practices with telephone triage, the triaging clinician will explain the research to a parent suggesting the child might be suitable to participate and ask if they are willing to discuss the study at the appointment.

Verbal assent to eligibility screening

In the consultation the clinician will enter a read code relating to ear problems, into the TRANSFoRM electronic data platform, to identify whether the child is potentially eligible. This will generate a pop-up window containing 4 questions, one of which asks whether the parent or guardian with legal responsibility for the child is present to give informed consent. All four questions must be answered "Yes", for the clinician to proceed to the eligibility screening criteria. The clinician must explain the study to the parent and ask if they are happy for the child to be checked for eligibility. If the parent agrees and the child appears willing, the clinician will record the parent's verbal assent and complete the eligibility assessment.

The parent's verbal agreement for the clinician to screen the child for eligibility must be documented in the medical notes, e.g. "discussed study, [name of parent] happy for [name of child] to be screened."

Prior to informed consent

If the child is eligible, the recruiting clinician must satisfy themselves that the parent (and the child, if old enough) have understood what the study involves, and they are willing to take part.

The clinician will give the parent the summary PIS, offering them an opportunity to read it. The clinician must ensure that the study is explained at a level that is understood, offering opportunities for questions to be asked, satisfactory answers to be given and for understanding to be communicated.

To give truly informed consent, potential participants need to understand the following:

- The purpose of the research;
- The practicalities and procedures involved in participating/their role if they agree to participate in the research;
- The benefits and risks of participation and, if appropriate, the alternatives therapies;
- How data about them will be managed and used;
- How information will be provided to them throughout the study;
- That they can withdraw from the study at any time, without giving any reason and without compromising their future treatment;
- The insurance indemnity arrangements for the conduct of the research where appropriate;
- That the research has been approved by a research ethics committee (RCN 2005).

Prior to assent

The recruiting clinician must satisfy themselves that the child, if old enough, has understood what is being asked of them within the study (at an age-appropriate level), and is willing to take part.

The clinician will give the child the CIS, asking them to read it and helping if necessary. The clinician must ensure that the study is explained at a level that is understood, offering opportunities for questions to be asked, satisfactory answers to be given, and for understanding to be communicated.

Should the child not wish to give assent, the clinician must record this on the participant registration details form on TRANSFoRm.

Basis of informed consent and assent in REST

- Good communication is interactive and seeks to involve the child;
- Medical jargon and difficult language should be avoided;
- Information given should be enough but not overwhelming;
- Directing simple questions about the study to the parent or child helps ensure their comprehension;
- Enough time should be allowed for parents to decide whether to take part;
- If parents feel obliged or pressurised to consent, the consent procedure has failed;
- If the child is not willing to take part, this over-rides the informed consent of the parent and the clinician should not proceed with recruitment.

Completion of the consent and assent forms

If the clinician is happy that the parent (and the child, if old enough) have understood what the study involves, and they are willing to take part, the consent and assent forms can be completed:

- The clinician must ensure that the consent form is signed and dated by the person who conducted the informed consent discussion and the parent, and that boxes are initialled by the parent, not ticked.
- If applicable, the child should be asked to write their name on the assent form. This will then be signed and dated by the person taking assent. If the child (of any age) is not able to write their name, the clinician or parent may annotate the form to confirm that assent has been sought and either given verbally or implied by the child's behaviour.

Management of REST consent forms

One hard copy of the consent form is printed by the TRANSFoRm platform, and is managed as follows:

- The parent must initial the boxes, print their name, and sign and date the hard copy;
- The person taking consent must print their name, and sign and date the hard copy;
- The person taking consent must write the PID number on the form once randomisation has taken place;
- **Original hard copy:** the person taking consent will:
 - Photocopy the consent form and give the copy to the parent to take away;

- Fax or scan/send by secure NHS encrypted email the original consent form to the Bristol study centre (before the end of the same working day as recruitment);
- Scan it into child's medical record;
- Store it in the study site file, to be collected at the end of the study.

Management of REST assent forms

One hard copy of the assent form is printed by the TRANSFoRm platform, and is managed as follows:

- The person taking assent and the child will complete, sign and date the hard copy;
- The child can write their name in their own way, i.e. it is acceptable for only a first name to be written;
- The person taking assent must write the PID number on the form once randomisation has taken place
- **Original hard copy:** the person taking assent will:
 - Photocopy the assent form and give the copy to the parent to take away;
 - Fax or scan/send by secure NHS encrypted email the original assent form to the Bristol study centre (before the end of the same working day as recruitment);
 - Scan it into child's medical record;
 - Store it in the study site file, to be collected at the end of the study.

Corrections to consent and assent forms

Any corrections should be carried out in accordance with GCP guidelines, i.e. using red ink, a clear line is drawn through the error, and is dated and initialled by the clinician.

Ongoing consent

The study team will ensure that consent and assent are ongoing through the telephone follow-up process: at each call the research nurse will check that the parent and child are happy to continue taking part in the study. If it becomes apparent that the child's assent is not ongoing, the Research Nurse should discuss with the parent and jointly decide whether participation should continue.

The study team will ensure that the participating parent has full contact details for the study, via the PIS.

Qualitative interviews consent

From those parents that indicate that they are willing to be contacted about taking part in a qualitative interview on their written consent form, a purposeful sample will be selected in relation to study arm, site, child's age, ethnicity and socioeconomic status. Of those who agree to take part in a telephone interview, the researcher will ask the parent to provide their verbal informed consent before the interview. The researcher will explain participation, the right to withdrawal, confidentiality and data recording and if the participant agrees to participate in the telephone interview, the researcher will turn on the audio recorder and ask the participant to confirm they consent to the interview being audio recorded, the use of anonymised quotes being used to illustrate findings, and understand their right to withdraw at any time.

9 Quality Control Measures

All primary care sites will go through the study sponsor GLP before the study is initiated at any recruiting site, to ensure that all staff are appropriately qualified to take consent and have received the study training including requirements for paediatric consent.

The research team will check all copies of consent/assent forms as they are received at the Bristol study centre on the day of recruitment. If any errors are noticed, the team will notify the primary care site recruiter by email of the errors, ask the recruiter to correct the errors on the original hard copy and resend the corrected form(s) to the study team.

The REST study monitoring plan will include checking that the informed consent and assent processes are being followed.

10 Related Documents

REST_PIS_v2.0_20180510

REST_Summary_PIS_v2.0_20180510

REST_CIS_6-10_v2.0_20180510

REST_CIS_11-16_v2.0_20180510

REST_Protocol_v7.0_20181031

71955_REST_Site_Agreement_v1.1_20180831

Rest_Monitoring_Plan_v3.0_20181127

European Medicines Agency (2008): Ethical considerations for clinical trials on medicinal products conducted with the paediatric population - Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use (ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethical-considerations-paediatrics_en.pdf)


University Hospitals Bristol NHS Foundation Trust (2014): the informed consent of children and young people in clinical trials v2.0 (12 Apr 2011, reviewed 12 Feb 2014).

11 Additional Guidelines


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12 Appendix


12.1 *REST_Consent_v3.0 20181031*




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 initialised by the parent for the child to be included in the study)

- 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.
- 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.
- 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.
- 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.
- I am willing to complete a questionnaire 3 months after study entry (online or on paper) about my child's health.
- That my child's medical records and data collected during the study, may be looked at by NHS-authorized 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.
- That my child can take part in the above study.

The following points (8-12) are optional:

- I am willing to collect a stool sample from my child on day 14 and 3 months after study entry.
- I am willing for my child's stool sample to be retained for future research in microbial infections.
- 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.
- 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.
- (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.

**INITIAL
boxes**

Child's Name (please print):

Parent's Name (please print):

Parent's signature:

Date:

Consenting Clinician's Name (please print):

Clinician's signature:

Date:

Paperwork management instructions: Complete one copy.

- Send to Bristol Trial Centre via secure fax: or encrypted email **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).

The Runny Ear Study (REST) Parent Consent Form

v3.0 31/10/2018

12.2 REST_Child_Assent_6-16_2.0_20181031

the runny ear study

CHILD ASSENT FORM (Age 6-16 Years)

Please circle the answer you agree with:

- | | | | |
|--------------------------------------------------------------|-----|---|----|
| 1. Has a doctor or nurse explained this study to you? | Yes | / | No |
| 2. Did you understand? | Yes | / | No |
| 3. Have you asked all the questions that you want? | Yes | / | No |
| 4. Did you understand the answers? | Yes | / | No |
| 5. It's okay to say no, at any time. Do you understand this? | Yes | / | No |
| 6. Do you want to take part? | Yes | / | No |

Please write your name here if you want to take part.

Your name:

Date:

Name of clinician taking assent:

Date:

Signature of clinician taking assent:

Person taking assent to write Participant ID here:

Paperwork management instructions: Complete one copy.

- Send to Bristol Trial Centre via secure fax or encrypted email **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).



IRAS ID: 229293



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

The Runny Ear Study (REST) Child Assent Form (6-16 Years)

v2.0 31/10/2018

Site Delegation Log

Site name:						Site PI:			
Name	Initials	Role	Start Date	End Date	Study Tasks (A-M)*	Signature of staff member	Signature of PI	Date	PI oversight required Y/N? **
Signature of PI confirming oversight for those staff members listed above where oversight is required (*YES):								Date:	

Study Task Codes	
<p>The eligibility and consent of children to the REST Study can be done under the following conditions:</p> <p>a. a GCP-trained doctor trained in the study procedures, OR;</p> <p>b. **a qualified, GCP-trained nurse or other healthcare professional trained in the study procedures with oversight from a GCP-trained doctor (oversight in this instance is signature of the PI on the delegation log to confirm oversight) Any discussion re: eligibility between the delegated person and doctor must be documented to indicate oversight.</p>	
<p>* Please list study tasks:</p> <p>A. Complete pre-eligibility screening form</p> <p>B. Eligibility confirmation (ELS)</p> <p>C. Informed consent (parent) and child assent: GCP-trained member of staff</p> <p>D. Informed consent (parent) and child assent: non-GCP trained member of staff with oversight</p> <p>E. Complete baseline data collection form</p> <p>F. Complete child/parent contact details form</p> <p>G. Sign FP10 prescription: only authorised prescribers as per their normal clinical work</p> <p>H. Give parent advice sheet on how to use antibiotic ear drops, delayed oral antibiotic or immediate oral antibiotics (as appropriate to the child's randomisation allocation)</p>	<p>I. Give parent REST Symptom & Recovery Questionnaire and explain a nurse will contact them the same working day as study entry</p> <p>J. Fax or securely email the consent form, assent form (if completed) and child/parent contact details to the Bristol study team on [redacted] or [redacted] by the end of the same working day as study entry</p> <p>K. Maintain the site file including replacing documents in response to amendment updates from the study team</p> <p>L. Securely store participant packs</p> <p>M. Complete the 3-months primary care notes data extraction</p>
<p>Instructions: For each member of staff: Against each task delegated by the Lead GP (PI), the responsible member of staff to complete the form. When complete, the Lead GP (PI) should sign and date the log. File original in the Site file. Send a copy to the Bristol study centre via secure fax [redacted] or encrypted email [redacted] Keep the log up-to-date - complete a new copy for additional members of staff. Send a copy to Bristol when any changes are made.</p>	

REST Study DPIA Risk Assessment

Ser.	Risk	Principle/Right	Impact	Likelihood	Risk
RSK001	Personal information is collected without a clear purpose or lawful basis	P1	M	L	
RSK002	The organisation doesn't comply with basic standards and expectations for information security and records management	P6	M	M	
RSK003	Poor-quality information may lead to decisions that impact negatively on individuals	P4, R3, R8	H	L	
RSK004	Collection methods may become unjustifiably intrusive	P2	M	L	
RSK005	The PERFoRm system loses the ability to identify when personal data has been accessed	P6	M	L	
RSK006	Data processor ceases operation (bankruptcy etc)	P1	H	L	
RSK007	Data processor moves data outside of EEA	P1	H	L	
RSK008	Clinical staff (processors) may not provide the participant information sheet prior to data collection	P1	H	L	

Ser.	Ref		Recommendation/Requirement
REC001	RSK001	Maintain a clear privacy notice outlining subjects' rights	Requirement
REC002	RSK002	Ensure staff are up-to-date on mandatory DP training and awareness of Records Retention Schedule both corporate and local	Requirement
REC003	RSK003	Ensure that the accuracy of data is regularly reviewed and that requests for alteration of data (if received) are actioned in a timely manner	Requirement
REC004	RSK004	Ensure that any change to collection of data is proportionate to needs of project	Requirement
REC005	RSK005	Ensure that staff are up-to-date on mandatory DP training and that only those who need to access the data are permitted to do so	Requirement
REC006	RSK006	Ensure that data can be ported to another provider if necessary	Recommendation
REC007	RSK007	Ensure that appropriate contractual safeguards are in place to ensure that data remains in the EEA	Requirement
REC008	RSK008	Ensure there is a process to routinely assess procedural adherence	Requirement

STANDARD OPERATING PROCEDURE FOR:

Secure Transmission of Study Documents

SOP Details:

Number: SOP-REST-XXXX	Version: 1.0	
Author(s): Annie Sadoo Title: REST Research Administrator		Date: 07/11/2018
Authorised by: Title:		Date:
Date operational:		
Date to be reviewed:		

Review History:

Review Date:		Reviewed By:	
Review amendments:			
Amended date:		Amended by:	
Authorised date:		Authorised by:	

Review Date:		Reviewed By:	
Review amendments:			
Amended date:		Amended by:	
Authorised date:		Authorised by:	

Review Date:		Reviewed By:	
Review amendments:			
Amended date:		Amended by:	
Authorised date:		Authorised by:	

Review Date:		Reviewed By:	
Review amendments:			
Amended date:		Amended by:	
Authorised date:		Authorised by:	

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1 Document History

Revision	Date	Author	Changes
1.0	07/11/2018	Annie Sadoo	None, this is the first draft

2 Purpose

This document outlines the responsibility of all staff working on the REST Study to adhere to data protection regulations and to take every measure to ensure that patient identifiable information is not made available to unauthorized persons or groups and treated in a manner to risk inappropriate disclosure.

This is the reference document for the study and should be used by all recruiting site staff, and all members of research and administrative Centre staff working on the study.

The research team will implement security measures that restrict the transfer and holding of person identifiable, confidential and sensitive data.

3 Scope

A secure fax or encrypted email medium must be used for the exchange of study management information including patient identifiable and clinical data between primary / secondary care clinical teams at recruiting clinical sites, REST Study research staff at study Centres and, the UH Bristol Research and Innovation team (acting as the independent study monitor).

This includes the exchange of routine recruitment data and urgent notification of patient safety data.

Sending identifiable patient information by the usual email route is not secure as it is not encrypted. If it were intercepted this would constitute a data breach.

NHSmail is a service available to NHS organizations that ensures confidentiality between all its users.

4 Abbreviations

MHRA	Medicines and Healthcare products Regulatory Agency
SAE	Serious Adverse Event
SUSAR	Serious Unsuspected Adverse Reaction
UH Bristol	University Hospitals Bristol NHS Foundation Trust

5 Procedure

5.1 Urgent Notifications

1. In keeping with study protocol, MHRA guidelines, EU directive and UK Clinical Trial Regulations key members of staff must be informed in the event a participant experiences a serious adverse event or serious unexpected adverse event.
2. The following documents relate to urgent notifications to study centres and UH Bristol monitoring team. Designated personnel will fax the completed documents in timeframes stipulated on the respective forms to the appropriate named recipient.
3. Documents relating to urgent notifications:
 - SAE Reporting Forms:
 - SAE/SUSAR Initial Report Form
 - SAE/SUSAR Follow-up Report Form
 - GP sites SAE instructions summary

5.2 Routine Recruitment Information

1. Bristol study centre staff need to know in real time when a parent and child have consented to participate in the study along with their contact details to initiate and enable patient follow-up.
2. Designated Clinical site staff will fax / email a copy of the following documents to the Bristol study Centre:
 - Parent consent form
 - Child assent form (if applicable)
 - Participant registration and contact details
3. These fax / email transmissions will contain the following patient identifiable and sensitive data:
 - Parent and Child's surname and forename

- Child's date of birth
 - Child's NHS number
 - Parent's home and email address, telephone number
4. Other documents to send to the local study centre via secure fax transmission / encrypted email in timeframes stated on the respective forms or relevant SOPs:
- Staff CVs and GCP certificates

6 Quality Control Measures

1. One of the most common breaches of confidentiality occurs when documents containing patient identifiable information are sent by fax. To minimize this, the fax machine should be placed in a secure location where information cannot easily be seen by unauthorized persons. The research and administrative team will ensure, as far as practicable, that data cannot be intercepted or seen by anyone other than the research team.
2. Use the REST Study fax cover sheet (Appendix 1) when sending a fax.
3. Contact the named fax recipient with an email or telephone call to let them know the fax is being sent. The named recipient must reply to confirm the fax is received.
4. Only use the REST Study NHSmail encrypted account – [REDACTED], from your own @NHS.net email address to communicate participant identifiable information.
5. File copies of the transmission verification reports where appropriate:
 - Clinical sites in your REST Study Site File
 - Study centre in your REST Study Master File

7 Related Documents

REST Study Fax Cover Sheet (Appendix 1)

8 Additional Guidelines

1. Refrain from sending faxes to the study centre if they are not going to be seen for some time and whenever possible send transmissions within office opening times.
2. Do not leave information unattended whilst a fax is being transmitted.
3. If possible, store the fax number in the machine memory or assign a speed dial number to the REST Study.

9 Appendix 1 – REST Study Fax Cover Sheet

**DATE:**

The information contained in this fax is **CONFIDENTIAL** and intended for the named recipient only. If you are not the named recipient you must not copy, distribute or disseminate this information, or disclose its contents to any person. If you have received this fax in error, please notify the sender immediately.

Thank You

Send to:

- Bristol Study Centre
 - UH Bristol Monitoring Team – SAEs/SUSARs only
- (*delete as necessary)

Attention:**Fax Number:**

- (Bristol Study Centre)
 - (UH Bristol Monitoring Team – SAEs/SUSARs only)
- (*delete as necessary)

From:**Site Name:****Fax Number:****Number of Pages, Including Cover:**☐ URGENT☐ URGENT: SAE/SUSAR REPORT
FOR UH BRISTOL MONITOR☐ REPLY ASAP☐ PLEASE COMMENT☐ PLEASE REVIEW☐ FOR YOUR INFORMATION**COMMENTS:**

fax cover

Population Health Sciences
Bristol Medical School
University of Bristol
Canyng Hall, 39 Whatley Road
Bristol, BS8 2PS
Unsecure email: [REDACTED]
Encrypted email: [REDACTED]

TRANSFoRm – the essential guide



A practice's essential guide to using TRANSFoRm

Who needs to read what?

Admin

Recruiters

Contents

1. Before you start- the installation instructions for admin staff

Uninstalling the REST app

1.1 Installing the REST App – pages 4-5

1.2 How do I know it has been successfully installed? – page 5-7

2. Things to know before you start

When you've had it installed on your own computer-here's what you need to do

2.1 Testing the Dummy Patient – page 8

2.2 Essential things to remember (quirks of the system) – page 9

2.3 Codes and Diagnoses to trigger the TRANSFoRm pop-up – page 10

3. Troubleshooting – page 11

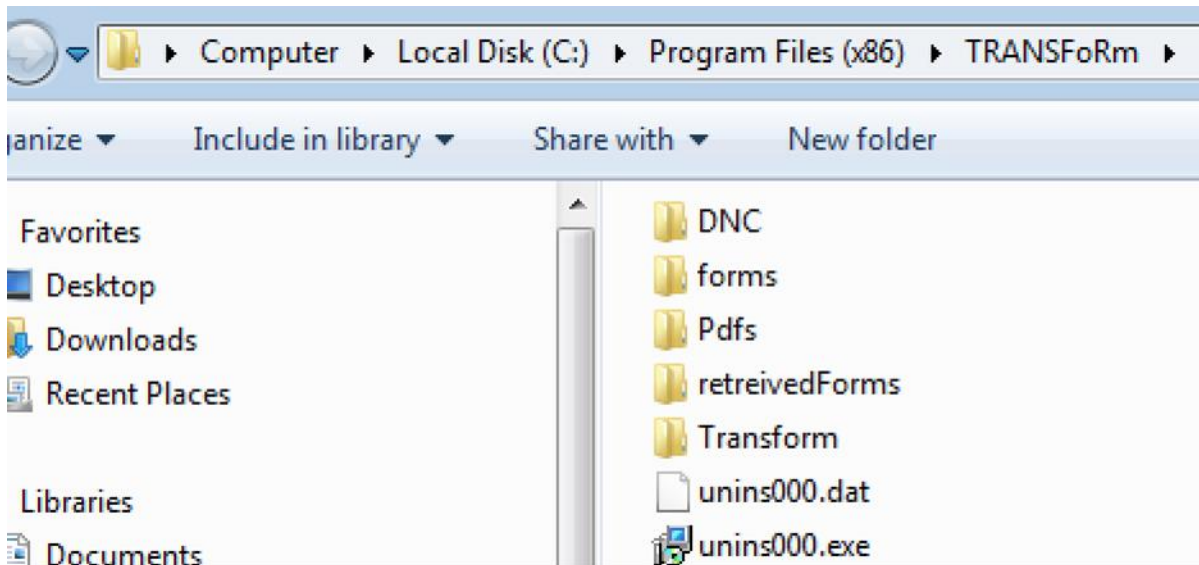
Security - the trial management platform is located on a server that supports encryption, therefore all data transmitted by the local REST app is encrypted during communication with the server and also kept encrypted on the allocated database.

1. Before you start - the installation instructions for Admin staff

Uninstalling the REST app

You may already have a version of TRANSFoRm installed. If so, please complete the below steps before attempting to install the new version.

- In Windows Explorer, go to C:\Program Files (x86)\TRANSFoRm\
- Double-click on the file labelled as unins000.exe (shown in the image below)



- Delete the TRANSFORM folder. The uninstallation has ended.

Now please follow steps below to install the new version of the app.

Before starting –

- Go to SystmOne and select “User” from the menu across the top of the screen
- Then select “User Preferences”
- Then type “SNOMED” into the search box at the top left of the window that pops up
- Ensure that both “Show Read codes” and “Show associated SNOMED code if available” are ticked

1.1 Installing the REST App

Before you install you must be sure you have **full administrator rights**.

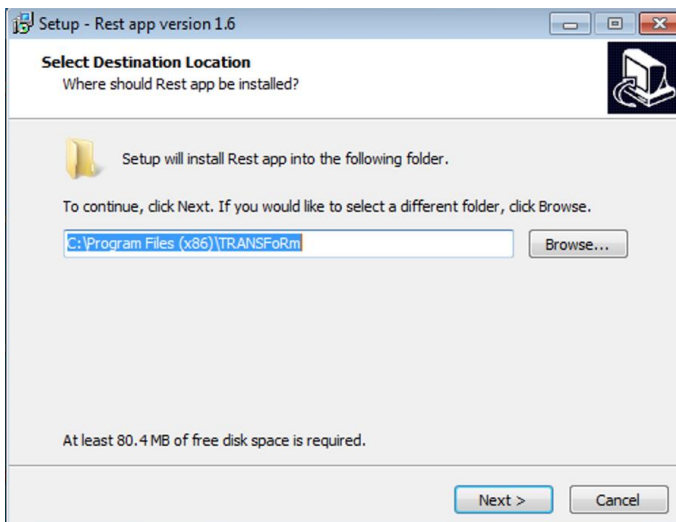
Step 1 - To begin, download the installer from our server at:

<https://www.rest-study.uk/downloads/InstallRESTapp.exe>

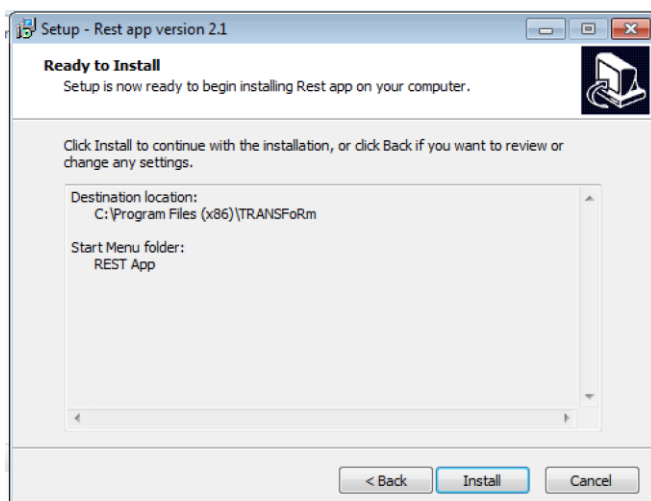


Step 2 - On the first screen, you must select the location of the installation. By default, it should look like the one below. If yes, click **Next**, otherwise, click **Browse** and select the location:

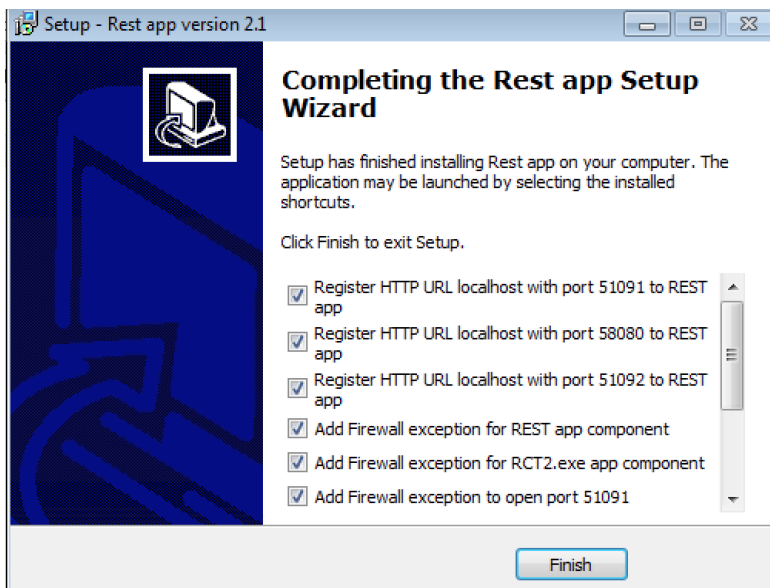
C:\Program File (x86)\TRANSFoRm



- On the next screen that appears simply select **Next**.
- The file is now ready to install. Click **Install** as shown in the screen below.



Step 3 - On the screen as shown below, please click **Finish**.

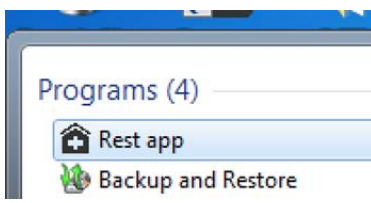


1.2 How do I know it's installed?

Testing the app runs for an admin user

The first time that the REST app is launched by each user of SystmOne, a message from SystmOne will be displayed asking you to allow 3rd party software, i.e. the REST app, to use SystmOne's API. **You must confirm the interaction**, otherwise our app will not be able to check for eligibility on patients at your practice.

Step 4 - To test that the app is installed correctly, **first open SystmOne and login**. Then double click on the icon located on your desktop or in the Windows app search icon (see below).

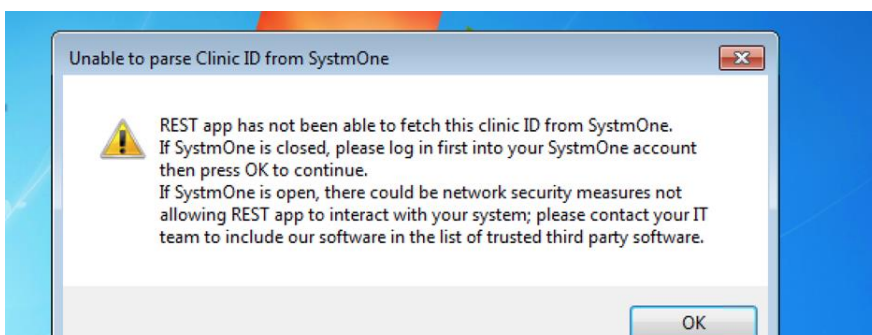


At this point - both the TRANSFoRM DNC (RCT2.exe) and the REST app should be running in the task bar.

Look for these icons →

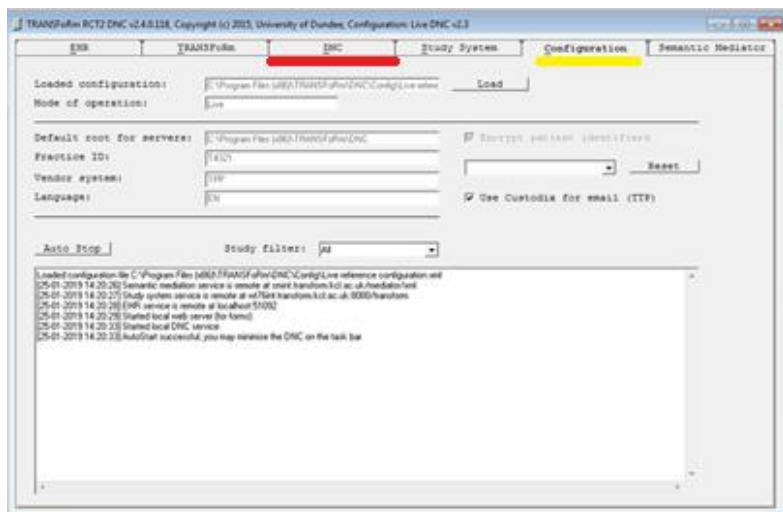


If you have not logged-in to SystmOne, you may encounter this message:



The REST app is attempting to parse your clinic ID from SystmOne, so log into your account and then press OK.

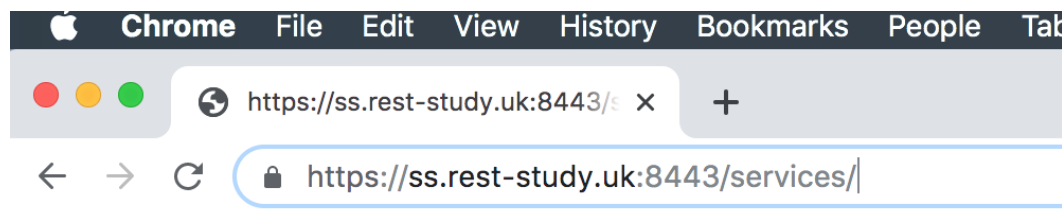
Step 5 - Double-click on the grey DNC app (**just once**), it may take a few seconds to maximise the window on your screen. Then, confirm that it looks like the image below:



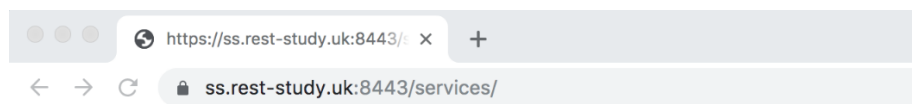
- The last line on the **configuration** tab must read “AutoStart successful, you may minimise the DNC on the task bar”.
- The line on the **DNC tab** **should not** begin with the word “Failed”.

Step 6

To find out whether there is a security measure in place to stop interactions among not recognised components, please write the following address into your favourite browser in the PC where TRANSForm has been installed, then press the ENTER button:



If connections **are allowed**, then you will receive an error response from our server (error because this is not the appropriate way of interacting with the server) similar to the one shown below.



Whitelabel Error Page

This application has no explicit mapping for /error, so you are seeing this as a fallback.

Mon Nov 25 12:33:51 GMT 2019

There was an unexpected error (type=Not Found, status=404).

No message available

This error response is enough to let us know that the server has been reached and therefore no firewalls are in place. If the response is **not** similar to this one please contact your IT support and send them this userguide, so that they can use the information directly below and add our software in the database as a trusted component (and therefore allow connections outside your network).

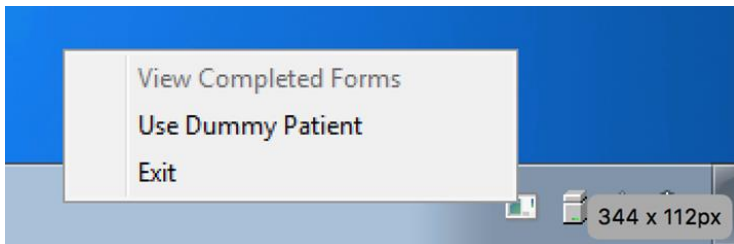
For the info of I.T support - Register port numbers 58080, 51091 and 51092 for HTTP connection among REST components and SystemOne.

Please note the addresses (to our remote servers)

o ss.rest-study.uk:8443

o sm.transform.kcl.ac.uk

Step 7 - You have now finished testing that the app launches and connects – please **EXIT** the app (**very important to always EXIT the app before logging out**).



- This is so that the clinician/nurse can test the workflow using their Windows credentials (they may not have admin privileges to Windows on their Pc).
- Log out as an admin user (we are assuming you may not be the clinician/nurse which will use the app).

2. Things to know before you start

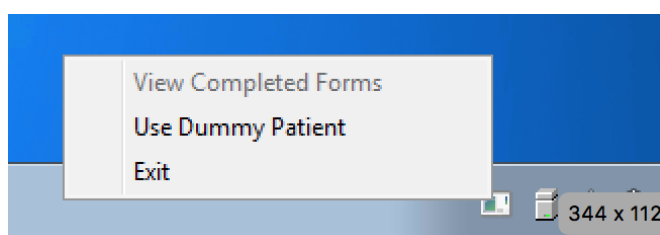
2.1 Testing the dummy patient

The first time that REST app is launched by each user of SystmOne, a message from SystmOne will be displayed requesting to allow 3rd party software (that is, the REST app) to use SystmOne's API. **You must confirm the interaction**, otherwise our app will not be able to check for eligibility on patients at your practice.

Step 1 - Log in (the REST app should begin automatically in a few seconds).

Step 2 - Open SystmOne and log in.

Step 3 - Right-click on the REST app and select **"Use Dummy Patient"**.



- Please only click the **"Pre-eligibility Screening Form"** (form 1 – see below) to test the dummy patient.

Step 4 - Click the radio buttons and submit. If no issues, the app is working correctly!



2.2 Essential things to remember (quirks of the system)

1. Please close the apps from your task bar (see below – right click and exit) and then restart the REST app from your desktop each morning after you've logged-in (**only if you don't shut down your computer each night**).



2. Informed consent must be completed on paper with the parent/guardian - see below:

A hard copy of the parent consent form **MUST** be printed and completed by the parent and clinician **BEFORE** the "Consent Form" page is submitted.

If the child is 6-16yrs, a link for the Child Assent Form will appear below the circled Consent Form link when the child's date of birth is entered. A hard copy must be printed and completed by the child and clinician **BEFORE** the "Consent Form" page is submitted.

3. If you have an older version of the app installed, the pop-up can appear **behind** the SystmOne screen (if you have SystmOne maximised to full screen) when you enter a relevant diagnosis code/term for a potentially eligible patient. A sound plays and the REST App icon does appear and flash on your taskbar at the bottom of the screen (please see example below). If you click the icon the pop-up will come to the front of the screen.

REST App Icon & Pop-Up with SystmOne screen open



REST App Icon

REST Pop-Up

- If you don't have SystmOne maximised to full screen, you will see the pop-up in the bottom right-hand corner as expected.

2.3 Codes and Diagnoses to trigger the TRANSFoRm pop-up

Read Code Browser

Browser Synonyms Formulary QOF QOF Clusters Templates Settings

Enter text to search Search

CTV3 Description	CTV3 Code	SNOMED Code
Acute otitis media	X00ip	3110003
Acute suppurative otitis media	F520.	194281003
Acute right otitis media	F527.	194289001
Acute left otitis media	F526.	194288009
Acute non-suppurative otitis media	F510.	359609001
Acute bilateral otitis media	F528.	194290005
Acute non-suppurative otitis media - serous	F5101	194240006
Acute otitis media with effusion	XE2QD	270490007
Acute suppurative otitis media NOS	F520z	194281003
Acute suppurative otitis media - tympanic membrane ruptured	F5201	86279000
Recurrent acute otitis media	F525.	194287004
Acute suppurative otitis media - tympanic membrane intact	F5200	14948001
Acute myringitis without otitis media	F540.	194311006
Recurrent acute suppurative otitis media	X00iq	232251007
Acute non-suppurative otitis media NOS	F510z	359609001
Acute non-suppurative otitis media - mucoid	F5102	52353000
Acute allergic serous otitis media	F5104	59275002
Acute allergic mucoid otitis media	F5105	8326008
Acute non-suppurative otitis media - sanguinous	F5103	77478005
Recurrent acute non-suppurative otitis media	X00ir	232252000
[X]Other acute non-suppurative otitis media	FyuP0	359609001
Unspecified acute tympanitis	F5401	194311006
Acute suppurative otitis media due to disease EC	F5203	194282005
Acute allergic sanguinous otitis media	F5106	17866004

SNOMED hierarchy

- Acute otitis media (3110003)
 - Acute exudative otitis media (19399000) ✗
 - Acute left otitis media (194288009)
 - Acute bilateral otitis media (194290005)
 - Acute myringitis (297009)
 - Acute myringitis without otitis media (194311006)
 - Acute necrotising otitis media (360595002) ✗
 - Acute otitis media with effusion (270490007)
 - Acute bilateral otitis media with effusion (7271000119107) ✗
 - Acute persistent otitis media (84261000119106) ✗
 - Acute right otitis media (194289001)
 - Acute bilateral otitis media (194290005)
 - Acute secretory otitis media (359609001)
 - Acute mucoid otitis media (52353000)
 - Acute allergic mucoid otitis media (8326008)
 - Acute sanguinous otitis media (77478005)
 - Acute allergic sanguinous otitis media (17866004)
 - Acute serous otitis media (194240006)
 - Acute allergic serous otitis media (59275002)
 - Acute seromucinous otitis media (8304007) ✗
 - Acute suppurative otitis media (194281003)
 - Acute suppurative otitis media due to another disease (194282005)
 - Acute suppurative otitis media with spontaneous rupture of ear drum (86279000)
 - Recurrent acute suppurative otitis media with spontaneous rupture of ear drum (1082561000119104) ✗
 - Acute suppurative otitis media without spontaneous rupture of ear drum (14948001)
 - Recurrent acute suppurative otitis media (232251007)
 - Recurrent acute suppurative otitis media with spontaneous rupture of ear drum (1082561000119104) ✗
 - Acute transudative otitis media (35183001) ✗
 - Recurrent acute otitis media (194287004)
 - Recurrent acute non-suppurative otitis media (232252000)
 - Recurrent acute suppurative otitis media (232251007)
 - Recurrent acute suppurative otitis media with spontaneous rupture of ear drum (1082561000119104) ✗

3. Troubleshooting

3.1 During installation

- If the configuration and DNC tabs do not match what is shown in **Step 5** then this could be due to an external firewall or antivirus – please contact your IT service.
- If you are having issues with the pop-up not appearing when you enter a relevant diagnosis code or phrase into SystmOne then please press **‘Enter’** to submit that diagnosis - this should ensure that the pop-up is triggered.
- Please refer to **section 2.3** for a list of codes that will trigger the pop-up. Writing things such as “ear pain” or “ear discharge” will not trigger the pop-up.

If the above troubleshooting does not work, please contact the REST study team:

Kathryn –

Kate –

Sue –

Annie –

Study mobile phone –