DUTY: Diagnosis of Urinary Tract Infections in Young Children Study						
	Site ID	Patient ID	- AA			

### SECTION 1: SCREENING FORM (Research Nurse/CSO to complete)

### **Inclusion Criteria**

Please exclude if the answer is 'NO' to any of the following:

Aged I	pefore their fifth birthday?	□ Yes	🗆 No
Acute	illness ≤28 days?	🗆 Yes	🗆 No
First ti	me in DUTY study?	□ Yes	🗆 No
Ability	of parent/carer to understand & give informed consent?	□ Yes	🗆 No
	he child have any urinary tract or constitutional symptoms (generally unwell)? uestions below (* see also examples):		
Answe	er Yes to at least one of the screening questions to be eligible:	□ Yes	□ No
0	Has the child been generally unwell (e.g. fever/feeling hot, generally not right, tired, irritable, crying more than usual, recently 'failing to thrive')?	🗆 Yes	□ No
0	Has the child had abdominal/loin pain or colic or vomiting or not eating/feeding as normal?	□ Yes	□ No
0	Has the child 'not been themselves' (e.g. clingy; not interested in what's going on; not playing well; low energy/tired; sleeping more or less than usual; irritable or not settling; crying more than usual)?	🗆 Yes	□ No
0	Has the child had any changes relating to passing urine (e.g. pain, changes in frequency, changes in continence, changes in urine smell or appearance or blood	□ Yes	□ No

### **Exclusion Criteria**

Please exclude if the answer is 'YES' to any of the following:

Recently (≤28 days) or currently in any research study	🗆 Yes 🗆 No
Presenting with trauma/injury as the predominant concern	🗆 Yes 🗆 No
Has taken oral or IV/IM antibiotics in the past 7 days*	🗆 Yes 🗆 No
Currently taking systemic (oral/IV or IM) steroids for > 2 weeks (e.g. prednisolone or dexamethasone inhaled steroids are acceptable)	🗆 Yes 🗆 No
Currently or recently (≤28 days) on chemotherapy or other immunosuppression (e.g.anti-rejection medications following renal transplant)	🗆 Yes 🗆 No
Current use of urinary catheter (including intermittent use within past month)	🗆 Yes 🔲 No
Previous bladder surgery	🗆 Yes 🗆 No
Spina bifida or neurogenic bladder	🗆 Yes 🗆 No
Due to laboratory transport pick up times, urine sample would not have reached lab in the next 24 hours (e.g. Friday afternoon in GP surgeries).	🗆 Yes 🗆 No
* Use of topical antibiotics does not exclude participation	

Use of topical antibiotics does not exclude participation

## Inclusion Criteria Examples for RNs/CSOs/clinicians\* e.g. 1) well child with a sticky eye/ear but no other symptoms – exclude e.g. 2) child with sticky eye/ear who is crying more than usual – include e.g. 3) child with cough but no other symptoms - exclude e.g. 4) child with cough and fever, or cough and difficulty breathing - include e.g. 5) child with cough, no fever, but not feeding well - include e.g. 6) child with diarrhoea, no fever, no abdominal pain, eating normally – exclude e.g. 7) child with diarrhoea and fever/abdominal pain/reduced appetite – include

If the child satisfies all inclusion and exclusion criteria please continue to the next section DUTY CRF SECTION 1-Screening Form v1.3 (17 October 2011) Page 1 of 1

DUTY: <u>D</u> iagnosis of <u>U</u> rinary <u>T</u> ract Infections in <u>Y</u> oung Children Study						
Site ID Patient ID						
SECTION 2: PARTICIPANT REGISTRATION FORM (Research Nurse/CSO to ask parent/carer)						
CRF Details						
DateTime (24 hr clock)RN/CSO Study ID $\square$ $\square$ $\square$ $\square$ $\square$ $\square$ $\square$ $\square$						
Consent obtained						
Recruited at own GP surgery?						
If No, please enter name of GP/surgery & address						
Child's Details						
First Name     Surname       Date of Birth     Gender						
D D / M M / Y Y Y F Female Male						
NHS Number						
Carer's Details						
First Name Surname						
Relationship to child please specify:						
Mother Father Other						
Address						
Postcode						
Contact Telephone Number Mobile Number						
Contact Notes						
DUTY CRF SECTION 2 - Participant Registration Form v1.4 (17 October 2011) Page 1 of 2						

DUTY: Diagnosis of Urinary Tract Infections in Young Children Study						
		Site ID Pat	ient ID			
Ethnicity						
Please describe your child	's ethnic group?					
White	□ British	🗆 Irish	□ Any other White background			
Mixed	□ White & Black Caribbean	□ White & Asian	□ Any other Mixed background			
	□ White & Black African					
Asian or Asian British	🗆 Indian	🗆 Bangladeshi	□ Any other Asian background			
	🗆 Pakistani					
Black or Black British	□ African	🗆 Caribbean	□ Any other Black background			
Chinese or Other Ethnic	□ Chinese	□ Any other				
Group						
Prefer not to answer	□ please tick here					
Additional Social Econ	aomia Quastians:					
Degree (or equivalent)	el of qualification? ( <i>Please d</i>	ross one box only) ∃ Diploma (or equiv	/alent)			
□ 'A' level		GCSE / 'O' level				
□ None	L	∃ Not given				
□ Other, please specify:						
Thinking about the cost of best describe your situat	of living and how it affects y tion?	/our household wh	nich of the following would			
☐ find it a strain to get by f	from week to week	□ able to manage without much difficulty				
□ have to be careful about	t money [	quite comfortably	off			
Not given						

DUTY CRF SECTION 2 - Participant Registration Form v1.4 (17 October 2011)

DUTY: <u>D</u> iagnosis of <u>U</u> rinary <u>T</u> ract Infections in <u>Y</u> oung Children Study							
	Site ID	Patient ID					

# SECTION 3: CASE REPORT FORM (Research Nurse/CSO to ask parent/carer)

## **Current Symptoms**

How many days (including today) has your child been unwell?								Enter n	umb <mark>er (</mark> 1	1- 28)	
Compared to yesterday is your child same, better or worse?											
Please rate yo	Please rate your overall impression of your child's current illness when at its worst from 0-10										
0	1	2	3	4	5	6	7	8	9	10	
Completel Well	ý									Extremely Unwell	

For each symptom, score symptom when it was at its worst during this illness.

Symptom			Severity		
	No Problem	Slight Problem	Moderate problem	Severe problem	Don't Know/ NA
Child 'not themselves'					
(e.g.: clingy; not interested in what's going on; not playing well; low energy/tired; irritable or not _settling; crying more than usual).					
Confused or Disorientated					
Disturbed sleep					
Fever at any time during this illness (fever is feeling hot or cold)					
Fever now or in the past 24 hours					
Chills or Shivering					
New generalised rash with this illness (not worsening of existing skin conditions)					
Nappy rash or similar					
Muscle aches or pains all over					
Headaches					
Refused feeds/eating less than normal					
Poor weight gain or weight loss (in the last month)					
Vomiting					
Diarrhoea (at any time)					
Diarrhoea (in the past 24hrs)					
Constipation in the last week					
Abdominal pain/tummy ache/pulling up legs					

DUTY CRF SECTION 3 - Case Report Form v1.2 (17 October 2011)

DUTY: <b>D</b> iagnosis of <b>U</b> rinary <b>T</b> ract Infections in <b>Y</b> oung Children Study							
	Site ID	Patient ID	- XH				

Symptom			Severity		
	No Problem	Slight Problem	Moderate problem	Severe problem	Don't Know NA
Passing urine more often					
Any changes in urine appearance (darker, cloudy, smelly or blood)					
If YES, please state:	□ Darker	□ Cloudy	□ Smelly	□ Bloody	□ Other
If Other, please describe:					
Pain/crying when passing urine					
Day or bed wetting when previously dry *					
Blocked or runny nose					
Cough					
Wheeze					
Short of breath, difficulty breathing or grunting					
Chest pains					
Earache or holding ear/s					
Sore throat					
More unwell compared to similar previous illnesses					
Any other symptoms		Yes		No	

\* Not applicable for children wearing nappies day & night

DUTY: Diagnosis of Urinary Tract Infections in Young Children Study								
		Site ID	Patie	ent ID				
			· ·	-	4 2 4 6			
	•							
Past Medical & Family H	-	blome vour chil	d has or has	had in the	nact Thora are			
These questions relate to also some questions conc					past. Mere are			
Not counting today, approxim nurse for this episode of illne		imes has your chi	ild previously	consulted a	a doctor or			
□0 □1 □2	□3 □4	□5 □6	<b>□7</b> □8	8 🗆 9	□10 <b>□10+</b>			
Does your child have any on	-going health prob	lems?		′es	□ No			
If YES, please indicate:								
🗆 asthma 🛛 diabetes	□ heart disease	high blood	pressure	🗆 learnir	ng disabilities			
□ other <i>please specify</i> :								
Was the pregnancy full term	for your child?		<u>ا</u> ا	′es				
If NO, please indicate:	□ Born Late	□ Born Early	lf E	arly, estima	te weeks:			
Was your child breastfed?			L D	′es	🗆 No			
If YES, for how long exclusive		3months	$\Box \ge 3$ months					
Were you ever told that your was abnormal in any way aft			/stem □ \	′es	□ No			
If <b>YES</b> , please give details:								
In boys ONLY – has your ch	hild been circumcis	sed?	C ۱	′es	□ No			
The next set of questions includes mother, father an We are asking these quest	d any brothers or	sisters who are	blood relati	ves of the				
Has your child or member of		een diagnosed w	rith □ Ƴ	′es	□ No			
vesico-ureteric or 'kidney' re	liux ?				🗆 Don't Know			
If YES, please indicate:	🗆 Child	□ Moth	er 🗆 F	ather	□ Sibling			
Has your child or any memb	er of your family ev	ver been diagnose	ed or □ ∖	′es	□ No			
treated for urine infections?					🗆 Don't Know			
If YES, please indicate:	🗆 Child	□ Moth	ner 🗆 F	ather	□ Sibling			
Does your child or any mem	ber of your family l	have any other		′es	□ No			
renal/urinary problem?	-				🗆 Don't Know			
If YES, please indicate:	🗆 Child	□ Moth	ner 🗆 F	ather	□ Sibling			
If YES, please give details:								

DUTY: Diagnosis of Urinary Tract Infections in Young Children Study							
		Site ID Pa	atient ID		¬ XH		
Medications							
Is your child currently taking a	ny medication?		□ Yes		□ No		
If YES, please indicate:							
<ul> <li>laxatives</li> <li>(e.g. lactulose, senna, modeci</li> </ul>	ol) (e.g. clenil)	beta <sub>2</sub> agonist in (e.g. salbutamol)	haler	☐ antih (e.g. pir	istamine iton)		
□ paracetamol	□ ibuprofen				,		
□ other medication (please p	rovide details):						
Toileting behaviour							
Does your child use nappies/p	oull-ups?		□ Yes		□ No		
If YES, please indicate:		🗆 Day	🗆 Nigh	nt	□ Both		
Approximately how many nappies/pull-ups has your child used in the last Estimate number							
How many times do you usua week?	lly bath or shower your	child in a normal	Estimate	e number			
Examination To be completed by Research	Nurse/CSO or respon	sible clinician					
					Please tick here if child refuses to be examined		
Temperature	<b>⊡</b> • □ °C	(range 35.0 – 42.0)					
DUTY standard 'Thermoscan'	thermometer used to c	heck temp?	□ Yes	🗆 No			
If NO, please indicate:	□ infrared ear	□ digital auxiliary	other:				
O <sub>2</sub> saturation	%	(range 80 – 100%)					
Pulse rate		(range 80 – 250 bpm)					
Respiratory rate		(range 20 – 80 rpm)					
Capillary refill time*	□ < 2 sec	□ 2-5 sec	□ > 5 se	ec			
* The Advanced Paediatric Life Supp and then recording the time it takes for			ressing on the	sternum fo	r 5 seconds		
Has the child's responsible cli	nician been informed o	f these results?	□ Yes		must be all children		

DUTY: Diagnosis of Urinary Tract Infections	s in <mark>Y</mark> oung Ch	nildren Study	DUTY
	Site ID	Patient ID	- AA

# SECTION 4: CASE REPORT FORM

(GP/responsible clinician to complete)

Clinicia	n's Deta	ails										
Cliniciar	n Name					1	1 1		1		-1 -1 -1	
Cliniciar	n Profes	sion					Doctor			□ N	urse	
Clinical	Examiı	nation										
Please	give yo	ur globa						-10				
	0	1	2	3	4	5	6	7	8	9	10	
Co	mpletely Well	1									Extreme	ly

In order to for all clinicians, irrespective of profession (nurse vs. doctor) or their location (GP practice vs. Walk in Centre vs. Emergency Department) to complete the global impression scale in a similar fashion, the following guidance has been derived:

A zero score is
appropriate for a
child who is
displaying no
'constitutional' upset.
Child is fully
conscious and alert,
aware/interacting
with their
surroundings (e.g.
smiling at parent/
guardian), feeding/
eating normally with
normal tone, normal
peripheral
circulation.
No fever, pain/
discomfort,
tachypnoea or
respiratory distress
at the time of
assessment.
assessment.

A score of 5 is appropriate for a child who is displaying 'constitutional' symptoms / signs warranting secondary care assessment but may not require admission. The primary care clinician would feel a secondary care assessment / period of observation was necessary. Emergency Department clinician would not feel happy to discharge without laboratory / radiographic tests or a period of observation.

A score of 10 is appropriate for a child who is displaying lifethreatening signs requiring immediate resuscitation such as unconsciousness and / or circulatory collapse.

DUTY: <u>D</u> iagnosis o DATE	f <u>U</u> rinary <u>T</u> r	act Infectio	ns in <u>Y</u> oung Site ID	Children Study Patient ID	
Please examine all of For each question, pl				abnormal, tick al	l that apply.
Examination			O	bservations	
Hydration	□ Normal	🗆 Some	e dehydration	Severe dehydr	ation D Not examined
Conscious Level	□ Normal		sy	Irritable	□ Not examined
General	□ Normal	🗆 Abno	rmal		□ Not examined
If abnormal please tick					
□ Pallor	□ Flushed	🗆 Jaun	dice	□ Distressed	Lymphadenopathy
□ Other (please	specify):				
Throat	🗆 N	ormal	□ Abnorma	l	□ Not examined
lf abnormal please tick	all that apply:				
□ Red or Inflame	ed ⊡S	wollen	🛛 Quinsy	Discharge of the second sec	or Pus
□ Other (please	specify):				
Ears	🗆 N	ormal	🗆 Abnorma	I	□ Not examined
lf abnormal please tick					
□ Pink		ed or Bulging		Fluid Level	
Acute Perforat	tion ⊔ C	hronic Perfora	ation		
□ Other (please	specify):				
Chest	🗆 N	ormal	🗆 Abnorma	I	□ Not examined
lf abnormal please tick					
Bronchial Brea	•	nilateral	Bilateral		
		nilateral	□ Bilateral		
		nilateral	Bilateral	🗆 Nasal Fla	ring
Recession (any intercostal/sub (any intercostal/sub	ocostal/ supra-c	lavicular)			ling
□ Other - <i>please</i>	specify:				
Abdomen	□ N	ormal	🗆 Abnorma	l	□ Not examined
If abnormal please tick					
□ Mass or Organ		sent If Yes	, please state:		
Loin Tenderne	ess —		∐ Supraput	bic Tenderness	
□ Other - <i>please</i>	specify:				

DUTY CRF SECTION 4 - Clinican CRF v1.3 (17 October 2011)

Page 2 of 4

DUTY: Diagnosis o	f <u>U</u> rinary <u>T</u> ract Infe	ctions in <u>Y</u> oung	Children Study	DUTY
DATE / /	,	Site ID	Patient ID	
Diagnosis and Plan	ned Management Pr	ior to Urine Dip	stick Results	
We would prefer if you	answer these question	s prior to seeing th	e urine dipstick resu	lts:
Are you currently awar	e of the urine dipstick re	esults?	□ Yes	🗆 No
What is your working d	iagnosis?			
	□ chest infection	bronchitis	bronchiolitis	🗆 pneumonia
exacerbation c (infective or non-ir		□ tonsillitis	□ otitis media	□ pharyngitis
🗆 UTI	gastroenteritis	□viral illness		
□ other <i>please</i> s	tate:			
How certain are you of	this diagnosis at this po	oint?		
🗆 uncertain	□ fairly certain	🗆 certain	very certain	
Before seeing dipstick	results, are you plannin	ig on treating this o	child with antibiotics?	
🗆 No	□ Yes [for suspected	ed UTI]	□ Yes [for other r	eason]
	If Yes: 🗆 immediate	e script	□ delayed script	
Before seeing dipstick hospital?	results, would you have	e referred this child	l to a paediatrician or	r admitted this child to
🗆 No	□ Yes [for suspected	ed UTI]	□ Yes [for other r	eason]
	□ N/A [recruited in	ED]		
If this child was NOT in	the DUTY study would	l you have request	ed a urine sample?	
			□Yes	🗆 No

DUTY: Diagnosis of Urinary Tract Infections in Young Children Study							
DATE / / /		Site ID	Patient ID				
Actual Management							
PLEASE COMPLET	E THE NEXT QUEST	IONS AFTER R	EVIEWING DIPSTICK				
Clinician Name							
Clinician Profession		□ Doctor	🗆 Nu	rse			
Has your working diagr	nosis changed?		□ Yes □	l No			
If Yes, please indicate							
	□ chest infection	□ bronchitis	□ bronchiolitis □	pneumonia			
exacerbation o (infective or non-in		□ tonsillitis	🗆 otitis media 🗌	pharyngitis			
	□ gastroenteritis	□viral illness					
□ other, <i>please</i> s	tate:						
How certain are you of	your diagnosis?						
🗆 uncertain	☐ fairly certain	🗆 certain	very certain				
Did you treat the child v	with antibiotics?						
□ No	Yes [for suspected]	ed UTI]	□ Yes [for other rease	on]			
	If Yes: 🛛 immediate	script	□ delayed script				
Please provide details o	of script:						
[GP surgery only] Was the child referred t	for same day urgent as	sessment in hospit	al?				
□ No	□ Yes [ for suspect	ed UTI]	□ Yes [for other reaso	on] □NA			
[ED only] Was the child admitted	to hospital for this illnes	ss?					
□ No	Yes [ for suspect	ed UTI]	Yes [for other reasonable]	on] □NA			

DUTY: Diagnosis of Urinary Tract Infection	s in <u>Y</u> oung Cł	nildren Study	DUTY
	Site ID	Patient ID	

# SECTION 5: CASE REPORT FORM (Research Nurse/CSO to complete)

## **Urine Collection**

Was a urine sample provided before the child left the surgery /discharged from ED? (* If 'No': ensure instructions are given to parent)	□Yes	□ No *
Which method was used to collect urine?		

Clean Catch	Nappy Pad	□В	ag	[	] Cat	the	ter			Suprapubic	aspiration	۱
Date child provided	(passed) urine			/		/						
Time child provided (	passed) urine	D	D :		M (2	24 h	Y r cloo	Y :k)	Y	Y		

If urine sample not provided, please given reason:

## **Dipstick Results**

Please record dipstick information:

Urine Dipstick Teste	ed: 🗆 Yes	□ No					
Date urine tested:		MM	/ 🗌	Y Y	Y	Time urine tested: :	]

	2 mins								
'	<b>A</b>	Leukocytes							
			Negative	Trace	+	++	+++		
		Nitrites							
			Negative	Positive	+	++	+++		
		Protein							
			Negative	Trace	+	++	+++	++++	
		рН							
a a		<b>P</b>	5.0	6.0	6.5	7.0	7.5	8.0	8.5
Read Time		Blood							
Real			Negative	Non-haem	Non-	Haem	Haem	Haem	Haem
1				Trace	haem ++	Trace	+	++	+++
		Specific Gravity							
			1.000	1.005	1.010	1.015	1.020	1.025	1.030
		Ketones							
			Negative	Trace	+	++	+++	++++	
:	30 secs	Glucose							
			Negative	Trace	+	++	+++	++++	

(SIEMENS - Multistix 8 SG)

DUTY CRF SECTION 5 - Case Report Form v1.2 (17 October 2011).doc

Page 1 of 2

DUTY: <u>D</u> iagnosis of <u>U</u> rinary <u>T</u> ract Infections	in <u>Y</u> oung Ch	nildren Study	DUTY
	Site ID	Patient ID	

# Sample Processing

Has the clinician taking responsibility for this child's care been informed of the dipstick results?	□ Yes
	NB this must be done for all children
Has the urine sample been divided, labelled with DUTY stickers and sent to the usual local NHS laboratory AND the central DUTY laboratory?	□ Yes: sent to NHS lab only.
	□ Yes: sent to both labs.
	□ No: dipstick test only.

\*NHS sample takes priority over the research lab sample if there is less than 2ml of urine.

Has the participant been given a £5 voucher?	🗆 Yes 🗆 No
Please record Voucher serial number here:	