

Evaluation of HIS-UK Study – Case Report Form (CRF)

Site ID

C	L	C	-	0	0	4
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Study Participant ID

4	2				
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1. Eligibility screening

Eligible

If not eligible (complete NERF)

2. Informed Consent

Obtained

Not completed (skip to 9)

Date:

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Consent form, and related study documents, were thoroughly reviewed by the subject.

Yes No

Subject had sufficient time to review the documents and ask questions.

Yes No

Informed consent obtained prior to any study related procedures.

Yes No

A copy of the documents (PIS and consent form) have been given to the subject.

Yes No

Name of person that obtained consent:

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Comments:

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3. Study registration

Completed

Not completed (complete 9)

4. Questionnaire

Completed

Not completed (complete 9)

5. Patient registration

Completed

Not completed (complete 9)

Patient Record ID

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6. Randomisation Completed Not completed (complete 9)

proHIS Arm

eHIS Arm

Control Arm

7. Intervention delivery Completed Not completed (complete 9)

Digital recording performed

Yes No

8. Samples collected Completed Not completed (complete 9)

Urine sample

Yes Not required Subject refused Postal-kit requested Postal-kit provided

Anal swab

Yes Not required Subject refused Postal-kit requested Postal-kit provided

Oral swab

Yes Not required Subject refused Postal-kit requested Postal-kit provided

9. Protocol violation

Comments /reasons:

Site PI Signature: _____ Date: _____

This form should be completed for each participant screened

Protocol Number, HIS-UK Study

Site ID

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Study Participant ID

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10. Chlamydia screening (registration, 6mths, 12 months)

Date of screening / kit sent	Method (Postal/in-clinic)	Test Type (Single/Triple)	Date of results transfer to study team
14/05/19	Postal	Single	28/05/19
20/05/19	In-clinic	Triple	31/05/19

Comments:

Site PI Signature: _____ Date: _____