

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

Site ID [ ][ ] - [ ][ ][ ][ ]

Study Participant ID [ ][ ][ ][ ][ ][ ][ ][ ]

1. Eligibility screening  Eligible  If not eligible (complete NERF)

2. Informed Consent  Obtained  Not completed (skip to 9)

Date: [ ][ ] / [ ][ ] / [ ][ ]

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: [ ]

Comments: [ ]

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 [ ]

**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

**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: \_\_\_\_\_