

Section M: Partner Notification Study

A. • HAS PATIENT ALREADY CONSENTED TO RANDOMISATION FOLLOWING HEALTH ADVISER CONTACT **YES**¹ **NO**²

- IF **YES** ENSURE YOU AND THE PATIENT HAVE COPIES OF CONSENT FORM AND PROCEED TO **SECTION N**
- IF **NO** COMPLETE THE FOLLOWING CHECKLIST FOR CONSENTING PATIENTS TO PARTNER NOTIFICATION STUDY IN CONJUNCTION WITH THE **CHLAMYDIA SCREENING STUDY 2 INFORMATION LEAFLET** (male or female version) WHICH SHOULD BE GIVEN TO THE PATIENT (**REMOVE FROM CLEAR SLEEVE**)

B. Place a tick next to each point	Tick ✓
1. State <u>the importance of treating partners</u> of anyone found to have Chlamydia <i>“We need to do this for all people found to have Chlamydia in order to stop the infection from spreading”</i>	
2. Explain that the Chlamydia study wants to find out the <u>best way of informing the partners</u> of their risk of infection <i>“We are comparing two ways of doing this: One involves being seen by myself at the GP surgery and the other involves being seen at a genitourinary clinic.....”</i>	
3. Explain that <u>all</u> patients found to have Chlamydia are being asked if they could help with this part of the study	
4. Explain that patients do not need to take part, it is <u>voluntary</u>	
5. Explain <u>what will happen if they do take part</u> (randomisation to 2 options, what these are)	
6. Assure patients that their <u>confidentiality will be protected</u>	
7. Ask them if they have <u>any questions</u>	
8. Seek consent	

• IF YOU HAVE COMPLETED THE CHECKLIST AND THE PATIENT **AGREES** TO PARTICIPATE COMPLETE THE PARTNER NOTIFICATION **CONSENT FORMS** (**REMOVE FROM CLEAR SLEEVE**)

- PRACTICE NURSE SIGNS BOTH CONSENT FORMS
- PATIENT SIGNS BOTH CONSENT FORMS
- PRACTICE NURSE RETAINS ONE COPY FOR RECORDS AND **ATTACHES PATIENT BARCODE** AND **RETURNS THIS COPY TO THE CLEAR SLEEVE**
- PATIENT RETAINS ONE COPY FOR THEIR RECORDS

• FOLLOWING COMPLETION OF CONSENT FORMS PROCEED TO **SECTION N**

• IF PATIENT **DECLINES** TO PARTICIPATE RECORD REASON IN **SECTION W** AND GOTO BOTTOM OF **SECTION N**

Section N: Randomisation

PLEASE ENSURE THAT YOU HAVE THE FOLLOWING INFORMATION TO HAND BEFORE PHONING:

- YOUR 2-DIGIT USER CODE
- YOUR 4-DIGIT PASSWORD
- YOUR 6 CHARACTER PRACTICE ID (You will only need the numeric part)
- THE 5-DIGIT UNIQUE ID NUMBER FOR THE PATIENT (FIRST PART OF BARCODE)
- THE CASE REPORT FILE (CRF)

BELOW ARE THE CODES FOR YOUR PRACTICE:

STICK CODES HERE

ONCE YOU HAVE ALL THE ABOVE INFORMATION TO HAND THEN PLEASE TELEPHONE **0117 928 7336**.

IF YOU FOLLOW THE VERBAL INSTRUCTIONS THEN EVERYTHING **WILL BE STRAIGHTFORWARD**.

FOR YOUR INFORMATION, ON THE BACK PAGE WE HAVE INCLUDED FULL INSTRUCTIONS COVERING EVERY EVENTUALITY SHOULD YOU WISH TO REFER TO THEM. YOU DO NOT NEED TO READ THE ADDITIONAL INSTRUCTIONS ON THE BACK PAGE.

IF YOU EXPERIENCE ANY DIFFICULTIES THEN PLEASE CONTACT THE CLASS CO-ORDINATING OFFICE ON 0117 928 7275.

PLEASE CROSS BOX

1. Which arm of the study has the patient been randomised to?

PRACTICE NURSE¹

GUM CLINIC²

DECLINED RANDOMISATION³

- IF RANDOMISED TO THE **PRACTICE NURSE** PROCEED TO **SECTION O**
- IF RANDOMISED TO THE **GUM CLINIC** PROCEED TO **SECTION P**
- IF PATIENT **DECLINES** RANDOMISATION OFFER CHOICE OF PRACTICE NURSE OR GUM

2. Would they prefer Partner Notification by:-

PRACTICE NURSE¹

GUM CLINIC²

REFERRED DIRECT TO GUM³

- IF **PRACTICE NURSE** PREFERRED PROCEED TO **SECTION O**
- IF **GUM** PREFERRED PROCEED TO **SECTION P**
- IF **DIRECT REFERRAL** TO GUM PROCEED TO **SECTION S**

Section O: Practice Nurse Partner Notification

Use this form to record details of all sexual partners in the last six months

To ensure comparability across the study please use the following definitions

Partner People who have had sex together – whether just once, or a few times, or as regular partners, or as married partners.

Sexual intercourse This includes vaginal (a man's penis in a woman's vagina), oral (a man's or a woman's mouth on a partner's genital area) or anal (a man's penis in a partner's anus) sexual intercourse.

A casual sexual partner is someone that you had sex on one or only a few occasions but who you do not intend to have sex with again.

A regular sexual partner is someone that you had sex with on more than one occasion and intend to have sex with again, or are currently in a relationship with.

Barcode	Contact Details To be completed by practice nurse
	A. Patient randomised ¹ Please circle

B. Contact Number (Ct code)	a. When did you last have sex <i>Date</i> dd/mm/yyyy	b. Was that a regular or casual partner (Circle answer)	c. Did you use a condom (Circle answer)	d. Full name of contact or initials or other form of identification <i>(if the index patient is willing to give it)</i>	e. Comments <i>(For example, any other details about contact)</i>
Contact 1	<input type="text"/> / <input type="text"/> / <input type="text"/>	Casual ¹ Regular ²	Yes ¹ No ²		
Contact 2	<input type="text"/> / <input type="text"/> / <input type="text"/>	Casual ¹ Regular ²	Yes ¹ No ²		
Contact 3	<input type="text"/> / <input type="text"/> / <input type="text"/>	Casual ¹ Regular ²	Yes ¹ No ²		
Contact 4	<input type="text"/> / <input type="text"/> / <input type="text"/>	Casual ¹ Regular ²	Yes ¹ No ²		
Contact 5	<input type="text"/> / <input type="text"/> / <input type="text"/>	Casual ¹ Regular ²	Yes ¹ No ²		
Contact 6	<input type="text"/> / <input type="text"/> / <input type="text"/>	Casual ¹ Regular ²	Yes ¹ No ²		

• ADD 'C4A' FOLLOWED BY NUMBER OF CONTACT SLIP E.G. C4A1, C4A2 TO THE Ct Code BOX OF EACH SLIP & ATTACH BARCODE LABEL TO EACH PARTNER NOTIFICATION SLIP GIVEN AND PROCEED TO SECTION Q

Section P: GUM Partner Notification

- PROVIDE THE PATIENT WITH THE STUDY FORM FOR PATIENT REFERRED TO GUM MANAGEMENT AND **ATTACH BARCODE LABEL** TO FORM (STUDY FORM CAN BE FOUND IN THE CLEAR SLEEVE)

1. Has the patient received the form? YES¹ NO²

2. Has the patient asked you to telephone now and make an appointment with the research health adviser? YES¹ NO²
(PATIENT MUST INITIATE THIS REQUEST)

- ASK PATIENT'S PERMISSION FOR GUM CLINIC TO CONTACT THEM IF THEY FAIL TO ATTEND AFTER 7 DAYS

3a. Does the patient agree to give you their telephone number? YES¹ NO²

- IF **YES** RECORD TELEPHONE NUMBER AND BEST TIME TO CALL (e.g. MORNING, BETWEEN 3PM AND 5PM, 9.30 AM) AND PROCEED TO **SECTION Q**
- IF **NO** PROCEED TO **SECTION Q**

3b. Home

3c. Work

3d. Mobile

3e. Friend

3f. Other

3g. (i) Best time to phone (ii) Number to use eg 3b, 3c, 3d etc

3h. (i) Best time to phone (ii) Number to use eg 3b, 3c, 3d etc

Section Q: Repeat Specimens

- PROVIDE PATIENT WITH REPEAT SAMPLE PACK AND EXPLAIN THAT A REPEAT SAMPLE SHOULD BE TAKEN IN **6 WEEKS'** TIME AND RETURNED BY POST IN THE PREPAID ENVELOPE PROVIDED. THE TEST IS REPEATED TO CHECK FOR RE-INFECTION
- **ATTACH PATIENT BARCODE LABEL -3 TO URINE POT AND/OR SWAB**
- **ATTACH PATIENT BARCODE LABEL -3 TO REPEAT SAMPLE: SHEET (3)**
- **WRITE SIX WEEK FOLLOW UP DATE ON SAMPLE PACK**

YES¹ NO²

1. Has the patient agreed to take the repeat sample pack?

- PROCEED TO **SECTION R**

Section R: Re-Contact

- INFORM PATIENT THAT THE RESEARCH HEALTH ADVISER WILL CONTACT THEM IN APPROXIMATELY 6 WEEKS BY TELEPHONE TO BE ASKED SOME QUESTIONS REGARDING THEIR CONTACT(S) AND AGAIN APPROXIMATELY 2 WEEKS AFTER THAT TO BE GIVEN THEIR REPEAT TEST RESULT (IF TAKEN)
- ASK PATIENT'S PERMISSION TO BE RE-CONTACTED

YES¹ NO²

1a. Has the patient agreed to be contacted?

- IF THE RESPONSE IS **NO** PROCEED TO **SECTION S**
- IF THE RESPONSE IS **YES** RECORD TELEPHONE/CONTACT DETAILS AND BEST TIME TO CALL (e.g. MORNING, BETWEEN 3PM AND 5PM, 9.30 AM) BELOW AND PROCEED TO **SECTION S**

1b. Home

1c. Work

1d. Mobile

1e. Friend

1f. Other

1g. (i) Best time to phone

(ii) Number to use eg 1b, 1c, 1d etc

1h. (i) Best time to phone

(ii) Number to use eg 1b, 1c, 1d etc

- PROCEED TO **SECTION S**

Section S: Trial and Nurse Led Partner Notification Refusal

- IF THE PATIENT HAS **DECLINED** TO ENTER THE PARTNER NOTIFICATION TRIAL AND NOT OPTED FOR PRACTICE NURSE INVOLVEMENT PROVIDE THEM WITH THE WHITE LOCAL GUM SLIP
- RECORD REASON FOR REFUSAL IN **SECTION W**
- ATTACH **PATIENT BARCODE LABEL** TO WHITE LOCAL GUM SLIP

YES¹ NO²

1. Have you provided the patient with the Local GUM Slip?

- A COPY OF THE LOCAL GUM SLIP CAN BE FOUND IN THE **CLEAR SLEEVE**
- **PROCEED TO SECTION T**

Section T: Qualitative Interview

- EXPLAIN THAT A RESEARCHER FROM THE STUDY TEAM MAY CONTACT THEM AT A LATER DATE TO ASK HOW THEY FELT ABOUT TAKING PART IN THE STUDY. THE PATIENT IS **NOT** BEING ASKED FOR **CONSENT** TO INTERVIEW BUT **AGREEING** TO BEING **CONTACTED**.

YES¹ NO²

1a. Does the patient agree to this?

- IF **NO** PROCEED TO **SECTION U**
- IF **YES** RECORD TELEPHONE NUMBER BELOW AND PROCEED TO **SECTION U**

<p>1b. Telephone number (record whether work¹, home², mobile³ other⁴.)</p> <p>Number code <input style="width: 20px; height: 15px;" type="text"/></p> <p>Telephone number <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/></p>	<p>1c. Best time to phone</p> <p>e.g. MORNING, BETWEEN 3PM AND 5PM, 9.30 AM</p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
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Section U: Consent for Results in Notes

- ASK PATIENT IF THEY WOULD LIKE TO HAVE THEIR TEST RESULT PUT IN THEIR MEDICAL NOTES

YES¹ NO²

1. Patient's response?

- IF **NO**, RETURN THE RESULT IN THE RESULTS ENVELOPE FOR RETURN TO STUDY CENTRE AND **PROCEED TO SECTION V**
- IF **YES**, DATE AND ATTACH THE APPROPRIATE **RESULT AND TREATMENT (IF ANY) STICKER** IN THE PATIENT'S MEDICAL RECORDS AND ENTER THE RESULT AND TREATMENT (IF ANY) WITH 'ClaSS study see medical notes' ONTO THE COMPUTER SYSTEM. RETURN THE RESULT IN THE RESULTS ENVELOPE FOR RETURN TO STUDY CENTRE AND **PROCEED TO SECTION V**

Section V: End Consultation

- THANK PATIENT FOR THEIR TIME AND ASSISTANCE WITH THE STUDY

Post-Consultation Checklist Have you ...?	Tick ✓
1. Asked patient if they require travelling/child care reimbursement For bus/train/taxi obtain receipt and double amount to cover return trip For car travellers record number of miles round trip to surgery - 40p per mile Round up to nearest pound Stick patients barcode into receipt book –Give patient a copy and keep carbon copy	
2. Posted repeat sample specimen(s) to PHLS in the white prepaid envelope, if taken in the surgery	
3. Placed results envelope, in CRF for return to study centre	
4. Placed Case Report File (CRF), in envelope provided for return to study centre	
5. Place returned case control questionnaire, in envelope provided for return to study centre	
6. Place Economics questionnaire, in envelope provided for return to study centre	
7. Telephone/Fax Study Centre to provide details of attenders/non-attenders (Appointments List)	
8. Telephone/Fax Research Health Adviser to provide: GUM referred patient details including telephone number(s) and best time to call	
9. Record any comments Section W	

Section W: Comments

- PLEASE RECORD ALL COMMENTS OR REMARKS THAT THE PATIENT HAS MADE ABOUT PARTICIPATING IN THE STUDY HOWEVER MINOR THEY MAY APPEAR TO BE.
- IF YOU FELT THIS WAS A PARTICULARLY DIFFICULT, UNUSUAL OR PROBLEMATIC CASE FROM YOUR POINT OF VIEW OR FROM THE PATIENT'S, THEN PLEASE EXPLAIN WHY BELOW.

Your comments are particularly important to the social researchers for the identification of potential case studies to follow up

1. Comments:

2. RECORD END TIME OF CONSULTATION

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(Please use 24 hour clock)

TELEPHONE RANDOMISATION

Below are details covering every option. Many of these messages will only be heard if you do not press the appropriate keys when asked.

Getting Started

After about 3-5 seconds you will be greeted with the following message:

"Hello, you have reached the randomisation centre for ClaSS, the Chlamydia Screening Study. Please press the '' button on your telephone to continue."*

Press the '*' button as instructed and you will hear a message saying *"Thank you."* If you do not press it, or if your telephone does not support tone dialling, then you will hear a message *"Sorry the '*' button was not detected. Please try again."*

This message will be repeated a further 2 times. If you still do not respond after the 3rd prompt you will hear a message saying *"Sorry the '*' button was not detected. This call will now be terminated."*

Entering Nurse ID and Password

You will be asked to enter your 2-digit user code as follows: *"Thank you. Please enter your 2-digit user code"*. If you do not enter it then you will hear a message *"Sorry your user code was not detected. Please try again."*

You will be asked to enter your 4-digit password as follows: *"Thank you. Now enter your 4-digit password."* If you do not enter it then you will hear a message *"Sorry your password was not detected. Please try again."*

Entering Practice ID

If you have entered a valid user code and password then then you will hear the following message: *"Your identity has been recognised by the system. Please enter the 5-digit numeric part of your practice ID."*

If you have not entered a valid combination then you will hear a message *"Your identity has not been recognised and you will now be disconnected."*

If you have not entered a practice ID then you will hear a message *"The numeric part of your practice ID was not detected. Please try again."*

If you have not entered the correct practice ID value then you will hear a message saying *"You are not authorised to randomise patients for this practice."*

Confirmation

Once a valid patient ID has been entered you will be asked to confirm it as follows: *"You wish to randomise the patient with unique identifier xxxxx. Press '0' to confirm that this is correct or '1' to re-enter the number."*

If the number was correct then press '0'. If it was incorrect then press '1' and re-enter it when prompted. If you do not press either button then you will hear a message *"No response was detected. Please try again."*

Randomisation Result

You will then hear one of the following messages depending upon which arm the patient has been randomised to:

"This patient has been allocated to partner notification and the Genital urinary medicine clinic" or

"This patient has been allocated to partner notification in the GP surgery."

You will then be prompted to document everything as follows:

"Please ensure that the treatment allocation is correctly documented in the registration box of the case report file. If you'd like the treatment allocation to be repeated press 2. To continue press 3. Thank you for calling today."

If you press '2' then you will be reminded which arm was selected. Finally you will hear the message below: *"If you have experienced any difficulties please contact the ClaSS co-ordinating office on 0117 928 7275. This call will now be terminated."*