The STAMP Trial

CONSENT FORM – UK

Title of Project: STAMP: Screening with Tampons: Evaluating Diagnostic Accuracy for STIs and HPV and Assessing Participant Views

IRAS ID: 334064

Participant Identification Number for this trial: STP-UK-_ _ _

Chief Investigator: Dr. John Luke Twelves

		Please initial box
1	I confirm that I have read the information sheet dated, [XXXXXXX], for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Lindus Health, Tampon Innovations Ltd or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
3	I consent to being contacted by the research team for the purposes of trial follow up (including receipt of test results via text and/or email) and I understand that this will require me to provide my contact details to the research team and organisations supporting the research team to deliver the trial.	
4	I understand that I will be required to provide three samples as part of this trial. I agree to completing study activities as required including attending one clinic visit, completing study questionnaire, and completing sampling at home as required.	
5	I understand that the trial is experimental, and that it does not replace standard practice for STI/HPV/BV testing or any national screening programmes (e.g. cervical screening programme) which I should continue to participate in.	
6	I understand that my name, date of birth and contact details will be shared with third parties to enable them to conduct necessary trial procedures e.g. supply me with a testing kit.	
7	I agree to my General Practitioner (GP) or Doctor being informed of my participation in the study.	
8	I consent to Lindus Health Limited using my data to improve, develop and create new products and services. This may include using this data to: ● improve the study that I am taking part in; ● improve planning for future studies; ● create statistical analysis, build digital control groups and AI models.	

9	I understand that my personal data will be retained for at least 12 months from trial completion before it is deleted, or longer if required by regulation related to clinical trial activity. For example, any research documents with personal information, such as consent forms, will be held securely for 10 years after the end of the study as per trial regulation.	
10	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I agree to take part in the above study and if I choose to withdraw, data already collected will continue to be used.	
	ADDITIONAL (optional, not required for study participation)	
11	I agree to being contacted with my test results. I understand that the results are experimental, and that I should request repeat testing if the results detect BV, chlamydia or gonorrhoea. I should discuss the results with my health provider if I am concerned. (Being informed of your test results is optional and will not affect your study participation. If you agree to being contacted in this way, the research team will contact you with your test results once they are available.)	
12	I agree to my GP being contacted with any positive test results that indicate the presence of HPV, BV, Chlamydia or Gonorrhoea. I understand that the results are experimental. (Having your GP informed of your test results is optional and will not affect your study participation. If you agree to your GP being contacted in this way, the research team will contact them with your test results if any of them show a positive result.)	
13	I am happy to be contacted by the research team or sponsor to be invited to Focus Groups in the future. (Taking part in the Focus Group is optional and will not affect your study participation. If you agree to be contacted, the research team may contact you with details of the Focus Group. You can then decide whether you want to take part or not.)	
14	I agree for my anonymised extracted RNA/DNA to be stored and used in future research, here or abroad, which has ethics approval. (Consenting for future use of samples is optional and will not affect your study participation.)	

Name of Participant	Date	Signature

1 copy of the (electronic) informed consent form will be sent to the participant and 1 copy of the (electronic) informed consent form will be stored in the site file