

Participant Trial Number:

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Laparoscopic Versus Abdominal hysterectomy (LAVA)

TELEPHONE Consent Form

This consent form can be used if the participant is unable to give written or electronic consent to participate in the LAVA trial.

Before taking consent please ensure that you have a witness present who can verify that informed consent was taken (they do not have to be named on the LAVA Delegation Log).

Please read each of the statements to the potential participant and insert your initials in each of the boxes that the participant agrees with.

After consent has been taken please ask your witness to countersign the form.

Please send a copy of the completed consent form to the participant, and record the method by which this was done and date at the end of this form

Record in the participant's notes that they have consented to participate in the LAVA study by a telephone consent, and place a copy of this form in the participants notes.

Place the Master (wet ink signed) version of this form in the LAVA Site File.

Please send a copy of the completed Consent Form to the LAVA Trial Office at the University of Birmingham

In order to ensure best practise, oral confirmation of ongoing consent to participate in LAVA should be sought from the participant when they present for their procedure and this should be recorded in the participant's medical notes.

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Initials of the person
taking consent

1	I confirm that I have read and understand the participant information sheet (version __. __ and date __/ __/ ____) for the LAVA trial. I agree that I have had the opportunity to take time to consider my involvement in the trial and I have had the chance to ask questions, all of which have been answered to my satisfaction.	
2	I agree that my involvement in the LAVA trial is voluntary, and I am free to withdraw at any time without the quality of my medical care or my legal rights being affected. I agree that if I decide to withdraw from the trial, any information that has already been analysed cannot be withdrawn. . I understand that should I want to withdraw from the study then I will be contacted by a member of the study team and given the options described in the above participant information sheet about what other data can be collected from me and what happens to it , and that my response will be recorded on a withdrawal form.	
3	I agree that my hospital research team can provide a copy of my consent form, and relevant personal information including my name, home address, date of birth, telephone number, ethnicity, Body Mass Index (BMI), if I have had any caesarean sections, the size of my womb and other relevant details of my medical history including my hysterectomy to the researchers based at the University of Birmingham for use in the LAVA trial	
4	I agree that relevant sections of my medical notes, and all of the information provided by me in trial related questionnaires will be transferred to members of the LAVA research team at the University of Birmingham. I agree that collaborators of the LAVA trial, and authorised representatives from the study sponsor (The University of Birmingham), regulatory authorities and my NHS trust can access my data where relevant such as my taking part in this research and safety monitoring..	
5	I agree that my data will be anonymised and used in combination with that of others to produce research outputs such as reports, presentations, publications and websites connected to the LAVA trial. I understand that I will not be individually identified in any publicly available output.	

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6	I understand that all information collected from me for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018. This information will be stored securely by the University of Birmingham, which is the data controller for the LAVA trial, for a minimum period of 10 years.	
7	I give consent for members of the LAVA trial team to contact me by telephone, mobile, post, voice over the internet protocol - VOIP (e.g. Skype, Facetime etc) or email to request additional information such as missing data on questionnaires that I have completed.	
8	I agree that some anonymous information collected from me may be shared and/or made publicly available for other researchers to support other research in the future.	
9	I agree that my general practitioner(GP) is informed of my participation in the LAVA trial.	
10	<p>I agree to my study number and mobile telephone number being passed to an external company (Textlocal) who will send me text messages containing a link that will take me to a questionnaire hosted by the University of Birmingham telling them which of the recovery goals I set before my operation I have reached.</p> <p>I understand that only my study number and mobile telephone number will be passed to Textlocal and that these, will be securely encrypted whilst being stored by Textlocal. I understand that my data will not be used by Textlocal for any other purpose.</p> <p>I understand that Textlocal will securely delete all the information they hold on me at the end of the LAVA study.</p>	
11	I understand the information that has been given to me about the LAVA trial and I agree to take part in this study.	

Name of Person taking Consent *Date* *Signature*

Name of Witness *Date* *Signature*

<Insert local trust header>

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Copy of completed consent form sent to participant by (please tick relevant boxes):

	<i>Yes</i>	<i>No</i>	<i>Date sent (Day / Month /Year)</i>
<i>Post</i>			
<i>Email</i>			
<i>Fax</i>			
<i>Handed to Participant</i>			