


CONSENT FORM (01)		Local Trust Logo
Audio-recording Initial Recruitment Session		
PARTICIPANT ID		

Name of Person giving recruitment information _____

By signing this form and initialing each box I confirm the following;	Please INITIAL ALL boxes
I confirm that I have read and understood the Patient Information leaflet (version 3 13/06/18 for the audio recording of the initial recruitment session for the TOPSY Study. I have had the opportunity to consider the information, ask questions and have had them answered satisfactorily.	<input type="checkbox"/>
I understand that taking part in the study is voluntary and it may not benefit my own health.	<input type="checkbox"/>
I understand that I am free to withdraw at any time, without giving any reason, without my care or legal rights being affected. I understand that it may not be possible to remove my data from the study once data analysis has started and results are published.	<input type="checkbox"/>
I agree to the TOPSY study "initial recruitment discussion" being audio recorded.	<input type="checkbox"/>
I understand that the audio recordings and written versions of the recording will be stored safely and that it will not be possible to identify me to anyone outside the research team.	<input type="checkbox"/>
I agree that my data may be used when presenting the results of the research but that it will not be possible to identify me.	<input type="checkbox"/>

Your signature (participant) _____ Date _____

Your name in block capitals _____


To be completed by local TOPSY researcher taking consent

I confirm that I have explained to the person named above, the nature and purpose of the audio recording of the "initial recruitment discussion".

Your signature _____ Date _____

Your name in block capitals _____

COPIES: Original for ISF; 1 each for participant, TOPSY trial office and patient notes.

CONSENT FORM (02) Main TOPSY study		Local Trust Logo
A multicentre randomised trial of the effectiveness and cost-effectiveness of pessary self-management versus standard care to treat pelvic organ prolapse and improve quality of life.		
PARTICIPANT ID		

Part 1: By signing this form and initialling each box I confirm the following:

Please
INITIAL ALL
boxes

I confirm that I have read and understood the Patient Information leaflet (version 3 13/06/2018) for the TOPSY Study. I have had the opportunity to consider the information, ask questions and have had them answered satisfactorily.

☐

I am not pregnant.

☐

I understand my taking part in the study is voluntary and may not benefit my own health.

☐

I understand I am free to withdraw from the study at any time, without giving a reason and without my medical care or legal rights being affected.

☐

I understand that it may not be possible to remove my data from the study once data analysis has started and results are published.

☐

I understand that I have a 50% chance of receiving self-management training for vaginal pessaries and a 50% chance of receiving standard clinic based pessary management.

☐

I agree that relevant data and my contact details can be stored, confidentially and securely, by the study offices at Glasgow Caledonian University and University of Stirling.

☐

I agree to being followed up as part of the study which includes completing questionnaires at 6, 12 and 18 months.

☐

I understand that relevant sections of any of my NHS records and data collected during the research, may be looked at by responsible individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the TOPSY study. I give permission for these individuals to have access to my records.

☐

I give permission for the research team, where relevant, to have access to my routine NHS data for long term follow up (with relevant ethical approvals).


☐

I agree that my GP can be told that I am taking part in this research.

☐

I agree to take part in the above study.

☐

CONSENT FORM (02) Main TOPSY study		Local Trust Logo
A multicentre randomised trial of the effectiveness and cost-effectiveness of pessary self-management versus standard care to treat pelvic organ prolapse and improve quality of life.		
PARTICIPANT ID		

Part 2: By signing this form and initialling the relevant box I confirm that

	Please initial relevant boxes	
	Yes	No
I am willing for one of my appointments and/or telephone calls with the local "TOPSY research team" to be audio recorded.	<input type="checkbox"/>	<input type="checkbox"/>
I am willing to be contacted about taking part in an interview study.	<input type="checkbox"/>	<input type="checkbox"/>
I am willing to be contacted once the TOPSY study ends about relevant research relating to the TOPSY study.	<input type="checkbox"/>	<input type="checkbox"/>

Your signature (participant) _____ Date _____


Your name in block capitals _____

To be completed by local TOPSY researcher taking consent

I confirm that I have explained to the person named above, the nature and purpose of the TOPSY trial and the treatments involved

Your signature _____ Date _____

Your name in block capitals _____

CONSENT FORM (03) Interviews		Local Trust Logo
Exploring randomised women's views and experiences of prolapse symptoms and treatment with a pessary: An interview study linked to the TOPSY Study		
PARTICIPANT ID		

**Please
INITIAL
ALL boxes**

By signing this form and initialling each box I confirm the following:

I confirm that I have read and understood the Patient Information leaflet (version 3 13/06/2018) for the TOPSY Study. I have had the opportunity to consider the information, ask questions and have had them answered satisfactorily.

☐

I understand that taking part in the study is voluntary and may not benefit my own health.

☐

I understand that I am free to withdraw from the study at any time, without giving a reason and without my medical care or legal rights being affected. I understand that it may not be possible to remove my data from the study once data analysis has started and results are published.

☐

I understand that a member of the research team will interview me twice over the next 18 months and these interviews will be audio-recorded.

☐

I understand that the audio recordings and written versions of the recording will be stored safely and that it will not be possible to identify me to anyone outside the research team.

☐

I agree that relevant data and my contact details can be stored, confidentially and securely, by the study offices at the University of Stirling.

☐

I agree that my data may be used when presenting the results of the research, including quotes of things I have said, but that it will not be possible to identify me.

☐

I agree to take part in the above study.

☐

Your signature (participant) _____ Date _____


Your name in block capitals _____

To be completed by local team member taking consent

I confirm that I have explained to the person named above, the nature and purpose of the TOPSY trial and the treatments involved

Your signature _____ Date _____

Your name in block capitals _____

CONSENT FORM (04) Interviews		Local Trust Logo
Exploring women's views and experiences of prolapse symptoms and treatment with a pessary: An interview study		
PARTICIPANT ID		

By signing this form and initialling each box I confirm the following:

**Please
INITIAL ALL
boxes**

I confirm that I have read and understood the Patient Information leaflet (version 4 14/11/2018) for the TOPSY Study. I have had the opportunity to consider the information, ask questions and have had them answered satisfactorily.

☐

I understand my taking part in the study is voluntary and may not benefit my own health.

☐

I understand I am free to withdraw from the study at any time, without giving a reason and without my medical care or legal rights being affected.

☐

I understand that it may not be possible to remove my data from the study once data analysis has started and results are published.

☐

I understand that a member of the research team will interview me twice over the next 18 months by telephone and that the interviews will be audio-recorded.

☐

I understand that the audio recordings and written versions of the recording will be stored safely and that it will not be possible to identify me to anyone outside the research team.

☐

I understand that relevant data and my contact details can be held, confidentially and securely, by the study offices at the University of Stirling.

☐

I agree that my data may be used when presenting the results of the research, including quotes of things I have said, but that it will not be possible to identify me.

☐

I agree to take part in the above study.

☐

Your signature (participant) _____ Date _____


Your name in block capitals _____

To be completed by team member taking consent

I confirm that I have explained to the person named above, the nature and purpose of the telephone interview TOPSY study

Your signature _____ Date _____

Your name in block capitals _____

CONSENT FORM (05) Interviews		Local Trust Logo
Exploring health care professionals' views and experiences: An interview linked to the TOPSY study		
PARTICIPANT ID		

By signing this form and initialling each box I confirm the following:

Please
INITIAL ALL
boxes

I confirm that I have read and understood the Patient Information leaflet (version 3 13/06/2018) for the TOPSY Study. I have had the opportunity to consider the information, ask questions and have had them answered satisfactorily.

☐

I understand my participation is voluntary.

☐

I understand I am free to withdraw from the study at any time, without giving a reason and without my medical care or legal rights being affected.

☐

I understand that it may not be possible to remove my data from the study once data analysis has started and results are published.

☐

I understand that I will be interviewed once by telephone and that the interview will be audio recorded.

☐

I understand that the audio recordings and written versions of the recording will be stored safely and that it will not be possible to identify me to anyone outside the research team.

☐

I understand that relevant sections of any of my NHS records and data collected during the research, may be looked at by responsible individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the TOPSY study. I give permission for these individuals to have access to my records.

☐

I agree that my data may be used when presenting the results of the research, including quotes of things I have said, but that it will not be possible to identify me.

☐

I agree to take part in the above study.

☐

Your name in block capitals _____

Your signature (participant) _____ Date _____

To be completed by local team member taking consent

I confirm that I have explained to the person named above, the nature and purpose of the TOPSY health professional interview study

Your signature _____ Date _____

Your name in block capitals _____