Contents Page Section 3: Methods Section Documentation – Questionnaire

University College London Hospitals NHS
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3.1 SAFFRON Assessment of Eligibility Form

Assessment of Eligibility

Study ID ……. Date …….

1. SCREENING		
1.1.	**Three screening questions asked by treatment team**	Yes ☐ No ☐
	"Are you having any sexual difficulties/problems in your intimate relationships?"	Yes ☐ No ☐
	"Is this a problem for you?"	Yes ☐ No ☐
	"Would you like some help with this?"	Yes ☐ No ☐
1.2.	**Had treatment for a gynaecological cancer (cancer of the ovary, womb, cervix or vulva) more than 3 months ago**	Yes ☐ No ☐
1.3.	**Speaks English**	Yes ☐ No ☐
1.4.	**Over 18 years old**	Yes ☐ No ☐
2. **FSFI**		
2.1.	**FSFI Score**	
2.2.	**Below or equal to 26?**	Yes ☐ No ☐
3. EXCLUSION CRITERIA		
3.1.	**Currently receiving sexual therapy or psychotherapy**	Yes ☐ No ☐
3.2.	**Current drug or alcohol abuse problem**	Yes ☐ No ☐

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3.2 SAFFRON Patient Consent UCLH

Department of Women's Cancer
Gynaecological Cancer Research Unit
University College London
1st Floor Maple House
149 Tottenham Court Road
London, W1T 7NF

Patient Consent Form

Name of Trial: Developing a Stepped Approach to Improving Sexual Function after Gynaecological Cancer: a feasibility study (SAFFRON)

Name of Principal Investigator: Dr Sue Gessler

1.	I confirm that I have read and understand the information sheet version 2 dated 02/02/2015 for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	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.	☐
3.	I understand that relevant sections of any of my medical notes and data collected during the trial, may be looked at by appropriate individuals from the PRIMENT Clinical Trials Unit, University College London, the Sponsor (and representatives of the sponsor) and relevant regulatory bodies, or from the institution where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4.	I agree to my GP being informed of my participation in this trial	☐
5.	I agree to take part in the above trial.	☐

Name of Patient	Date	Signature
_____	_____	_____
Name of person taking consent (designated responsible person)	Date	Signature
_____	_____	_____

When completed: Take 4 copies. Original and 1 copy to be kept in medical notes and investigator site file, a copy to be given to the patient. In addition, send 3rd copy to CTU.

uclh University College Hospital | National Hospital for Neurology and Neurosurgery | Eastman Dental Hospital | Royal National Throat, Nose and Ear Hospital | Heart Hospital | Royal London Hospital for Integrated Medicine

University Hospitals Bristol NHS
NHS Foundation Trust
Department of Women's Cancer
Gynaecological Cancer Research Unit
University College London
1st Floor Maple House
149 Tottenham Court Road
London, W1T 7NF

3.3 SAFFRON Patient Consent Bristol

Patient Consent Form

Name of Trial: Developing a Stepped Approach to Improving Sexual Function after Gynaecological Cancer: a feasibility study (SAFFRON)

Name of Principal Investigator: Dr Sue Gessler

1.	I confirm that I have read and understand the information sheet version 2 dated 02/02/2015 for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	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.	☐
3.	I understand that relevant sections of any of my medical notes and data collected during the trial, may be looked at by appropriate individuals from the PRIMENT Clinical Trials Unit, University College London, the Sponsor (and representatives of the sponsor) and relevant regulatory bodies, or from the institution where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4.	I agree to my GP being informed of my participation in this trial	☐
5.	I agree to take part in the above trial.	☐

Name of Patient	Date	Signature
_____	_____	_____
Name of person taking consent (designated responsible person)	Date	Signature
_____	_____	_____

When completed: Take 4 copies. Original and 1 copy to be kept in medical notes and investigator site file, a copy to be given to the patient. In addition, send 3rd copy to CTU.

INFORMED CONSENT AND DEMOGRAPHICS

SAFFRON **Site:** _____ **Visit date:** D D M M Y Y Y Y **Visit:** **Baseline**

Screening ID: _____ **Participant Initials:** _____

1. INFORMED CONSENT

1.1. Date participant signed written consent form D D M M Y Y Y Y

1.2. Name of person taking informed consent _____

1.3. Date person taking informed consent signed written form D D M M Y Y Y Y

2. DEMOGRAPHICS

2.1. Date of Birth D D M M Y Y Y Y

2.2. Age ☐☐ years

2.3. Ethnicity

(please tick one)

White

- ☐ White British
- ☐ White Irish
- ☐ White Other

Mixed race

- ☐ White & Black Caribbean
- ☐ White & Black African
- ☐ White & Asian
- ☐ Other mixed background

Black or Black British

- ☐ Caribbean
- ☐ African
- ☐ Black Other

Chinese

- ☐ Chinese

Asian or Asian British

- ☐ Indian
- ☐ Bangladeshi
- ☐ Pakistani
- ☐ Other Asian background

Other ethnicity

- ☐ Other (please specify below)

_____

2.4. Living Situation

(please tick one)

- ☐ Living alone
- ☐ Living with partner
- ☐ Living with others (children, relatives etc.)

Priment™ Clinical Trials Unit

Completed by Print Name _____ Signature _____ **Completed on** D D M M Y Y Y Y

2.5. Highest completed level of education

(please tick one)

- ☐ Higher degree
- ☐ Degree
- ☐ A level (or equivalent)
- ☐ HNC/HND (or equivalent)
- ☐ NVQ (or equivalent)
- ☐ GCSE (or equivalent)
- ☐ No qualification
- ☐ Other (Please specify): _____

2.6. Employment status

(please tick one)

- ☐ Full time
- ☐ Part time
- ☐ Unemployed - seeking work
- ☐ Unemployed - not seeking work
- ☐ Home maker
- ☐ Retired
- ☐ On sick leave
- ☐ Student
- ☐ Other (Please specify): _____

3. DISEASE RELATED INFORMATION

3.1. Type of Cancer:	
3.2. Stage of disease (FIGO)	
3.3. Histological type	
3.4. Date of primary diagnosis (dd/mm/yy)	/ /

3.5. Disease recurrence Yes ☐ No ☐

Date (if applicable) (dd/mm/yy) _____

INFORMED CONSENT AND DEMOGRAPHICS

SAFFRON **Site:** **Visit date:** D D M M Y Y Y Y **Visit:** **Baseline**

Screening ID: **Participant Initials:**

3.6. Menopausal status at diagnosis (Menopause = 12 months without a period)

- ☐ Pre-menopausal
- ☐ Post-menopausal
- ☐ Unknown

3.7 Co-morbidity Yes ☐ No ☐

If yes, which one

- ☐ Renal disease
- ☐ Cardiac disease
- ☐ Respiratory disease
- ☐ Rheumatic disease
- ☐ Diabetes
- ☐ Liver disease
- ☐ Other (specify) _____

4. TREATMENT RELATED INFORMATION

4.1. Surgery Yes ☐ No ☐

4.2. Mode of surgery

- ☐ Laparatomy
- ☐ Laparoscopy
- ☐ Vaginal

4.3. Organs removed

- ☐ Uterus
- ☐ Ovaries/ adnexae
- ☐ Pelvic nodes
- ☐ Para aortic nodes
- ☐ Omentum
- ☐ Vagina
- ☐ Vulva
- ☐ Other

4.4. Radiotherapy Yes ☐ No ☐

4.5. Mode of radiotherapy

- ☐ External
- ☐ Brachytherapy

INFORMED CONSENT AND DEMOGRAPHICS

SAFFRON **Site:** _____ **Visit date:** D D M M Y Y Y Y **Visit:** **Baseline**

Screening ID: _____ **Participant Initials:** _____

☐ Chemotherapy

Number of cycles given: _____

☐ Hormonal Therpay

☐ Other (specify) _____

4.6. Time since primary treatment (dd/mm/yy)	/ /
4.7. Date of completion of last treatment (dd/mm/yy)	/ /

5. ECOG/ WHO Performance Status

☐ Fully active, no restrictions on activities

☐ Unable to do strenuous activities, but able to carry out light housework and sedentary activities

☐ Able to walk and manage self care, but unable to work. Out of bed more than 50% of waking hours

☐ Confined to a bed or chair more than 50% of waking hours. Capable of limited self-care

☐ Completely disabled. Totally confined to a bed or chair. Unable to do any self care.

☐ Death