



## Understanding the impact of cancer diagnosis and treatment on everyday life

# **BASELINE VULVAL CANCER CRF**

# FOR STAFF USE ONLY

### **CRF** Completion Instructions

- This CRF is for completion by members of site staff NOT study participants
- Please complete the CRF when a patient has been recruited to the study
- Please complete as much of the CRF as possible
- If you have any queries, please contact the HORIZONS Coordinating Centre, email address <u>HORIZONS@soton.ac.uk</u>
- Please tick boxes when appropriate
- When you have completed the CRF, please keep a copy for your own records and return a copy to us, by post, fax or email along with the completed return cover sheet

Participant's Study ID			
Participant's date of birth	d d m m	у у у у	
Participant's weight kg	Ра	rticipant's height	cms
Participant's blood pressure (P which they were measured)	lease give the most	recently reported figures c	ind the date on
Systolic	mmHg	Date mea	sured
Diastolic	mmHg	d d m m	у у у у

Participant's tumour type (please tick one box)

Туре	Sub-type	
Vulval	Squamous cell carcinoma	
	Other (please describe on line below)	
	Not currently known	

Date of participant's current cancer diagnosis

(date that histological diagnosis was reported)

Participant's Study ID



Participant's FIGO stage (please tick one box OR tick the box indicating the FIGO stage is not currently known)

Stage 1 Cancer is only in the vulva and/or	Cancer is only in Cancer is $\leq 2$ cm and has grown $\leq 1$ mm deep into the skin	
perineum Stage 1B Cancer is >2cm OR is any size and has grown >1mm deep into the skin		
Stage 2 Cancer has spread	d to nearby tissue (eg. lower urethra, vagina, anus)	
Stage 3Stage 3ACancer hasCancer has spread to 1 lymph node that is $\geq$ 5mm OR 2 lymph nodes thespread to lymph<5mm		
groin	<b>Stage 3B</b> Cancer has spread to 2 or more lymph nodes that are <u>&gt;</u> 5mm OR cancer has spread to 3 or more lymph nodes that are <5mm	
	<b>Stage 3C</b> Cancer has spread to any number of lymph nodes and has spread outside the lymph node capsule	

FIGO stage not currently known



Participant's tumour grade (please tick one box)

Grade 1/low grade/well differentiated	
Grade 2/moderate/intermediate grade	
Grade 3/high-grade/poorly differentiated	
Grade not currently known	

Participant's Study ID		/		/				
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#### Participant's ECOG status (please tick one box)

ECOG 0 (the patient has no symptoms)	
ECOG 1 (the patient has symptoms but is ambulatory)	
ECOG 2 (the patient is bedridden less than half the day)	
ECOG 3 (the patient is bedridden half the day or longer)	
ECOG 4 (the patient is chronically bedridden and requires assis- tance with the activities of daily living)	

#### Has the participant had a previous diagnosis of cancer (please tick one box)



No

Unknown

If you answered "yes" to the above question, please provide some information about the patient's previous cancer(s) by completing the box(es) below

#### **PREVIOUS DIAGNOSIS 1**

Type of cancer	
Date of diagnosis	
Treatment received	
Date treatment ended	

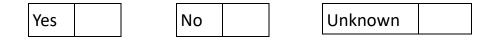
#### PREVIOUS DIAGNOSIS 2

Type of cancer	
Date of diagnosis	
Treatment received	
Date treatment ended	

Participant's Study ID		]/[		/					
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Has the participant had any genetic tests for inherited cancers?

(please tick one box)



If you answered "Yes" to the above question, please provide some information about the participant's other genetic test(s) by completing the table(s) below

Name of genetic test for cancer (1)	Result of genetic test
	Positive
	Negative
	Ambiguous/uncertain
	Awaiting result
	Unknown

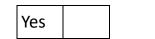
Name of genetic test for cancer (2)	Result of genetic test
	Positive
	Negative
	Ambiguous/uncertain
	Awaiting result
	Unknown

Is the participant pre or post menopause? (please tick one box)

Pre menopause	
Post menopause	
Unknown	

Participant's Study ID		
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Has a first degree relative of the participant (parent, sibling or child) been diagnosed with cancer? (please tick one box)





Unknown

If you answered "yes" to the above question, what type of cancer and when was

	Type of cancer	Age at diagnosis	Date of diagnosis
Relative 1			
Relative 2			
Relative 3			

#### Participant's HPV (Human Papilloma Virus) status (please tick one box)

HPV positive	
HPV negative	
HPV status unknown	

Participant's Study ID		]/			/				
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Has the participant ever had a positive result (borderline, low-grade squamous dyskaryosis, high grade dyskaryosis, abnormal glandular cells or glandular dyskayosis) following a cervical cancer smear test ? (please tick one box)

Yes, at least one positive cervical cancer smear test result	
No, only negative cervical cancer smear test results	
Cervical cancer smear test results unknown	

# Does the participant have any of the following co-morbidities (please tick all that apply)

Myocardial infarct	
Angina/coronary artery disease	
Congestive Heart Failure	
Cardiac Arrythmias	
Hypertension	
Venous Disease (PE/DVT)	
Peripheral Arterial Disease	
Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, asthma)	
Liver Disease (portal hypertension, chronic/acute hepatitis, cirrhosis)	
Stomach Ulcers or Inflammatory Bowel Disease	
Acute or Chronic Pancreatitis	
End-stage Renal Disease (chronic renal insufficiency, chronic dialysis, acute dialysis)	
Thyroid problems	



#### Participant's co-morbidities continued (please tick all that apply)

Diabetes Mellitus Type 1	
Diabetes Mellitus Type 2	
Stroke/TIA	
Dementia	
Paralysis (paraplegia or hemiplegia)	
Neuromuscular Condition (multiple sclerosis, Parkinson's, myasthenia gravis, other chron- ic neuromuscular disorder)	
Anxiety	
Psychiatric Diagnosis (schizophrenia, depression, bipolar disorder, recent suicide attempt)	
Osteoarthritis	
Rheumatoid Arthritis	
Other Rheumatological Disease (systemic lupus, mixed connective tissue disorder, poly- myositis, rheumatic polymyositis)	
HIV/AIDS	
Alcohol Abuse (or history of, must be accompanied by social, behavioural or medical compli- cations)	
Drug/Substance Abuse (or history of, must be accompanied by social, behavioural or medi- cal complications)	
Morbid Obesity	
Other (please give details)	

What is the participant's proposed treatment start date (main first-line treatment

for vulval	cancer)
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Please add your name and signature and the date that you completed this CRF

Name	Signature
Date	