

**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 Co-ordinating Centre, email address [HORIZONS@soton.ac.uk](mailto:HORIZONS@soton.ac.uk)**
- **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  m  y  y

Participant's weight \_\_\_\_ kg Participant's height \_\_\_\_ cms

Participant's blood pressure (*Please give the most recently reported figures and the date on which they were measured*)

Systolic \_\_\_\_\_ mmHg

Date measured

Diastolic \_\_\_\_\_ mmHg

d  m  y  y

Participant's tumour type (please tick one box)

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

Date of participant's current cancer diagnosis  d  m  y  y

(*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)

<b>Stage 1</b> Cancer is only in the vulva and/or perineum	<b>Stage 1A</b> Cancer is $\leq 2$ cm and has grown $\leq 1$ mm deep into the skin	
	<b>Stage 1B</b> Cancer is $> 2$ cm OR is any size and has grown $> 1$ mm deep into the skin	
<b>Stage 2</b> Cancer has spread to nearby tissue (eg. lower urethra, vagina, anus)		
<b>Stage 3</b> Cancer has spread to lymph nodes in the groin	<b>Stage 3A</b> Cancer has spread to 1 lymph node that is $\geq 5$ mm OR 2 lymph nodes that are $< 5$ mm	
	<b>Stage 3B</b> Cancer has spread to 2 or more lymph nodes that are $\geq 5$ mm OR cancer has spread to 3 or more lymph nodes that are $< 5$ mm	
	<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   /   /

Participant's ECOG status (please tick one box)

ECOG 0 (the patient has no symptoms)	<input type="checkbox"/>
ECOG 1 (the patient has symptoms but is ambulatory)	<input type="checkbox"/>
ECOG 2 (the patient is bedridden less than half the day)	<input type="checkbox"/>
ECOG 3 (the patient is bedridden half the day or longer)	<input type="checkbox"/>
ECOG 4 (the patient is chronically bedridden and requires assistance with the activities of daily living)	<input type="checkbox"/>

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

Yes

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	<input type="text"/>
Date of diagnosis	<input type="text"/>
Treatment received	<input type="text"/>
Date treatment ended	<input type="text"/>

**PREVIOUS DIAGNOSIS 2**

Type of cancer	<input type="text"/>
Date of diagnosis	<input type="text"/>
Treatment received	<input type="text"/>
Date treatment ended	<input type="text"/>

Participant's Study ID   /   /

Has the participant had any genetic tests for inherited cancers?

(please tick one box)

Yes	<input type="checkbox"/>
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No	<input type="checkbox"/>
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Unknown	<input type="checkbox"/>
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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	<input type="checkbox"/>
	Negative	<input type="checkbox"/>
	Ambiguous/uncertain	<input type="checkbox"/>
	Awaiting result	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>

Name of genetic test for cancer (2)	Result of genetic test	
	Positive	<input type="checkbox"/>
	Negative	<input type="checkbox"/>
	Ambiguous/uncertain	<input type="checkbox"/>
	Awaiting result	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>

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

Pre menopause	<input type="checkbox"/>
Post menopause	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

Participant's Study ID  /  /

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

Yes	<input type="checkbox"/>
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No	<input type="checkbox"/>
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Unknown	<input type="checkbox"/>
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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	<input type="checkbox"/>
HPV negative	<input type="checkbox"/>
HPV status unknown	<input type="checkbox"/>

Participant's Study ID   /   /

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	<input type="checkbox"/>
No, only negative cervical cancer smear test results	<input type="checkbox"/>
Cervical cancer smear test results unknown	<input type="checkbox"/>

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

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

Participant's Study ID   /   /

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 chronic neuromuscular disorder)	
Anxiety	
Psychiatric Diagnosis (schizophrenia, depression, bipolar disorder, recent suicide attempt)	
Osteoarthritis	
Rheumatoid Arthritis	
Other Rheumatological Disease (systemic lupus, mixed connective tissue disorder, polymyositis, rheumatic polymyositis)	
HIV/AIDS	
Alcohol Abuse (or history of, must be accompanied by social, behavioural or medical complications)	
Drug/Substance Abuse (or history of, must be accompanied by social, behavioural or medical complications)	
Morbid Obesity	
Other (please give details) _____	

What is the participant's proposed treatment start date (main first-line treatment for vulval cancer)

/   /

Please add your name and signature and the date that you completed this CRF

Name \_\_\_\_\_ Signature \_\_\_\_\_

Date

/   /