HORIZONS

UNIVERSITY OF Southampton

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**

- **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 ☐y ☐y ☐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 ☐d ☐m ☐m ☐y ☐y ☐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 ☐d ☐m ☐m ☐y ☐y ☐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)

Stage 1 Cancer is only in the vulva and/or perineum	**Stage 1A** Cancer is ≤2cm and has grown ≤1mm deep into the skin	
	Stage 1B Cancer is >2cm OR is any size and has grown >1mm deep into the skin	
Stage 2 Cancer has spread to nearby tissue (eg. lower urethra, vagina, anus)		
Stage 3 Cancer has spread to lymph nodes in the groin	**Stage 3A** Cancer has spread to 1 lymph node that is ≥5mm OR 2 lymph nodes that are <5mm	
	Stage 3B Cancer has spread to 2 or more lymph nodes that are ≥5mm OR cancer has spread to 3 or more lymph nodes that are <5mm	
	Stage 3C 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)	
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 assistance with the activities of daily living)	

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	
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 ☐☐ / ☐☐ / ☐☐☐☐

Has the participant had any genetic tests for inherited cancers?

(please tick one box)

Yes		No		Unknown	

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	

HORIZONS Baseline Case Report Form; Vulval. Version 2.0, 03/10/2018, IRAS Project ID: 202342, REC reference number 16/NW/0425

Page 5 of 8

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 | ☐ | | No | ☐ | | 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 □□ / □□ / □□□□

Has the participant ever had a positive result (borderline, low-grade squa-mous dyskaryosis, high grade dyskaryosis, abnormal glandular cells or glan-dular 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 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) ☐d ☐d / ☐m ☐m / ☐y ☐y ☐y ☐y

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

Name _____ Signature _____

Date ☐d ☐d / ☐m ☐m / ☐y ☐y ☐y ☐y