HORIZONS

UNIVERSITY OF Southampton

Understanding the impact of cancer diagnosis and treatment on everyday life

12 MONTH VULVAL CANCER CRF

FOR STAFF USE ONLY

CRF Completion Instructions

- **Please complete as much of the CRF as possible**
- **Please refer to your copy of the 6 month CRF when completing this 12 month CRF: please complete any additional treatment details that were not captured at 6 months (for example, additional treatments, or end dates of those ongoing at 6 months)**
- **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 |

Has the participant had any genetic tests for inherited cancers? (please tick one box)

Yes (already recorded in previous CRF)	
Yes (but not recorded in previous CRF)	
No	
Unknown	

If you answered "Yes (but not recorded in previous CRF)" 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	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Has the participant developed any NEW co-morbidities (which were not recorded in the baseline or 6 month CRF)? (please tick all that apply) in the tables below and overleaf)

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 etc.)	
Liver Disease (portal hypertension, chronic/acute hepatitis, cirrhosis etc.)	
Stomach Ulcers or Inflammatory Bowel Disease	
Acute or Chronic Pancreatitis	
End-stage Renal Disease (chronic renal insufficiency, dialysis etc.)	
Thyroid problems (hyperthyroidism, hypothyroidism etc.)	
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)	
Clinical diagnosis of anxiety	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Participant's new co-morbidities continued

Clinical diagnosis of depression	
Psychiatric Diagnosis (e.g. schizophrenia, bipolar disorder)	
Osteoarthritis	
Rheumatoid Arthritis	
Other Rheumatological Disease (systemic lupus, mixed connective tissue disorder, polymyositis, rheumatic polymyositis, scleroderma etc.)	
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) _____	
Other (please give details) _____	
Other (please give details) _____	

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

Pre menopause	
Post menopause	
Unknown	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

What treatments has the participant received **since those captured at 6 months**, please tick ALL that apply and write details in the spaces provided. Please add end dates for any treatments which were ongoing at 6 months (table continued overleaf).

Treatment type	**Specific treatment details**	**Tick if patient has received**	**Date of surgery or start date of other treatment (dd/mm/yyyy)**	**End date of treatment (if finished) (dd/mm/yyyy)**	**If course of treatment was not completed as planned, please give a reason why**
Neo-adjuvant chemotherapy	Drug(s), please give details _____		__ / __ / 20__	__ / __ / 20__	
	Neo-adjuvant chemotherapy number of cycles, please enter on line _____				
Neo-adjuvant radiotherapy	External radiotherapy		__ / __ / 20__	__ / __ / 20__	
	Number of radiotherapy fractions, please enter on line _____				
	Dose for each radiotherapy fraction please enter on line _____				
Surgery	Sentinel lymph node biopsy		__ / __ / 20__		
	Groin/inguinal lymph node dissection		__ / __ / 20__		
	Radical wide local excision / Wide local excsion		__ / __ / 20__		
	Radical partial vulvectomy / Partial vulvectomy		__ / __ / 20__		
	Radical vulvectomy		__ / __ / 20__		
	Pelvic exenteration		__ / __ / 20__		
	Vulval reconstruction		__ / __ / 20__		
	Plastics surgery (please describe) _____		__ / __ / 20__		
	Other surgery (please describe) _____				

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Treatment type	Specific treatment details	Tick if patient has received	Date of surgery or start date of other treatment (dd/mm/yyyy)	End date of treatment (if finished) (dd/mm/yyyy)	If course of treatment was not completed as planned, please give a reason why
Adjuvant Chemotherapy or Chemoradiation (please tick all that apply and give details for any radiotherapy below)	Cisplatin		__ / __ / 20__	__ / __ / 20__	
	Fluorouracil (5-FU)		__ / __ / 20__	__ / __ / 20__	
	Mitomycin		__ / __ / 20__	__ / __ / 20__	
	Carboplatin		__ / __ / 20__	__ / __ / 20__	
	Paclitaxel/Taxol		__ / __ / 20__	__ / __ / 20__	
	Capcitabine		__ / __ / 20__	__ / __ / 20__	
	Other (please describe below): _____		__ / __ / 20__	__ / __ / 20__	
	Chemotherapy number of cycles, please enter on line _____				
Radiotherapy	External radiotherapy		__ / __ / 20__	__ / __ / 20__	
	Number of radiotherapy fractions, please enter on line _____				
	Dose for each radiotherapy fraction please enter on line _____				
	Brachytherapy		__ / __ / 20__	__ / __ / 20__	
	Number of radiotherapy fractions, please enter on line _____				
	Dose for each radiotherapy fraction please enter on line _____				
Other	Other treatment e.g. clinical trial treatment (please describe) _____		__ / __ / 20__	__ / __ / 20__	

Participant's Study ID | | / | | / | | | | |

Has the participant had a **local** recurrence of their vulval cancer? (please tick one box)

Yes		No		Unknown	

If the participant has had a **local** recurrence, on what date was the recurrence diagnosed?

d	d	m	m	y	y	y	y

Since the participant's diagnosis of vulval cancer, has there been any evidence of distant metastatic disease? (please tick one box)

Yes		No		Unknown	

If you have answered "yes" to the above question, on what date was the metastatic disease diagnosed:

d	d	m	m	y	y	y	y

Please provide details of the site(s) of distant metastatic disease:

_____

Is the participant taking part in a clinical trial? (please tick one box)

Yes		No		Unknown	

If you answered "yes" to the above question, please give the NAME of the clinical trial the participant is taking part in

Name of clinical trial _____

Participant's Study ID | | / | | / | | | | |

Since the participant's diagnosis of vulval cancer, have they been diagnosed with another new primary cancer? (please tick one box)

Yes		No		Unknown	

If you answered "yes" to the above question, please provide some information about the participant's new cancer diagnosis by completing the table below

Type of cancer	
Date of diagnosis	__ / __ / 20___
Treatment received	
Date treatment ended (if finished)	__ / __ / 20___

What type of follow-up care is the participant receiving? (please tick ONE box)

Routine/regular hospital clinic based follow-up (medical or nurse led, face-to-face or by telephone)	
Primary care based follow-up	
Patient initiated follow-up (also known as patient triggered follow-up (PTFU), open access follow-up, or supported self-managed follow-up)	
If the participant is receiving patient-initiated follow-up, on what date were they discharged to this? d d m m y y y y	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Has the participant been referred to any of the following services and/or had a Holistic Needs Assessment? (please tick all that apply)

Participant has been referred to palliative care services	
Participant has been referred to psychological services If ticked, please provide route to referral (e.g. GP, Improving Access to Psychological Therapies) _____	
Participant has been referred to community services	
Participant has been referred for treatment related problems (e.g. urology, gastroenterology) If ticked, please provide more details below: _____	
Participant has had an HNA (holistic needs assessment)	

If the participant has died please give the date and cause of death:

Participant's date of death

d d / m m / y y y y

Cause of participant's death

1) a)	
1) b)	
1) c)	
2)	

Cause of death not known ☐

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

Name _____ Signature _____

Date CRF completed

d d / m m / y y y y