HORIZONS

UNIVERSITY OF Southampton

Understanding the impact of cancer diagnosis and treatment on everyday life

6 MONTH BREAST 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 baseline CRF when completing this 6 month CRF: the questions marked with a RED ASTERISK need only be answered if they were marked "not currently known", "unknown" or left blank at baseline**
- **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 tumour type (please tick one box below, OR tick to indicate the question was answered at baseline)*

This question was answered at baseline ☐

Type	Sub-type	
Breast	Invasive ductal breast cancer	
	Invasive lobular breast cancer	
	Other (please describe below)	
	Not currently known	

Date of participant's current cancer diagnosis (please add details OR tick to indicate the question was answered at baseline)*

This question was answered at baseline ☐

Date of current cancer diagnosis

(date that histological diagnosis was reported) d d m m y y y y

Participant's tumour TNM (Tumour-Node-Metastasis) stage at diagnosis (please add details OR tick to indicate the question was answered at baseline)*

This question was answered at baseline ☐

T _____ N _____ M _____

If TNM is unknown, please complete number staging details overleaf

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Participant's tumour number stage at diagnosis (please tick one box OR tick to indicate the question was answered at baseline)*

This question was answered at baseline ☐

Stage 1		
Stage 2	Stage 2A	
	Stage 2B	
Stage 3	Stage 3A	
	Stage 3B	
	Stage 3C	

IMPORTANT—YOU SHOULD HAVE ENTERED A TNM OR NUMBER STAGE FOR EACH PARTICIPANT, EITHER IN THIS CRF OR IN THE BASELINE CRF

Participant's tumour grade (please tick one box OR tick to indicate the question was answered at baseline)*

This question was answered at baseline ☐

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 ☐☐ / ☐☐ / ☐☐☐☐

Is the participant ER, PR or HER2 positive? (please tick three boxes)

	Positive	Negative	Unknown
ER			
PR			
HER2			

Has the participant been tested for BRCA1 or BRCA2 (please tick one box)*

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

If you answered "Yes (but not recorded in baseline CRF)" to the above question, was the result (please tick one box)

Positive for a mutation in BRCA1 or BRCA2	
Negative for a mutation in BRCA1 or BRCA2	
Ambiguous or uncertain	
Unknown	
Awaiting result	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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

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

If you answered "Yes (but not recorded in baseline 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 CRF)? (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 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	
Clinical diagnosis of depression	
Other psychiatric diagnosis (eg. schizophrenia, bipolar disorder etc.)	

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

Osteoarthritis	
Rheumatoid Arthritis	
Other Rheumatological Disease (systemic lupus, mixed connective tissue disorder, poly-myositis, 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) _____	

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

Pre menopause	
Post menopause	
Unknown	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

What was the participant's route to diagnosis (the route they took through the healthcare system before receiving a cancer diagnosis)? (please tick one box)

The participant was diagnosed:	
1. Following attendance at a screening programme (via the national screening programmes for bowel, breast and cervical cancers)	
2. During/following a hospital outpatient appointment which resulted from:	
i) An urgent GP referral for suspected cancer ("Two-week wait")	
ii) A routine GP referral (for symptoms which don't arouse suspicion of cancer but need investigating)	
iii) A referral from a different outpatient specialty (eg. ENT)	
3. During/following an admission to hospital which was:	
i) An inpatient elective	
ii) An emergency (after an emergency GP referral, during an A&E visit, whilst in hospital due to an emergency)	
4. Other (please give details) _____	
5. Unknown	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

What treatments has the participant received, please tick ALL that apply and write details in the spaces provided

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
Surgery	Wide local excision (breast conserving surgery)		__ / __ / 20___		
	Mastectomy		__ / __ / 20___		
	Sentinel node biopsy (SNBx)		__ / __ / 20___		
	Axiliary node clearance (ANC)		__ / __ / 20___		
	Other axiliary treatment please describe on line below) _____		__ / __ / 20___		
Breast reconstruction	Immediate reconstruction		__ / __ / 20___		
	Delayed reconstruction		__ / __ / 20___		
	Delayed reconstruction is planned but has not yet taken place				
Reconstruction type	Implant				
	Latissimus dorsi (LAD)				
	Deep inferior epigastric perforator artery (DIEP)				
	Tissue reconstruction with abdominal tissue (TRAM)				
	Nipple reconstruction				
	Other (please describe on line below) _____				

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
Radiotherapy	Breast		__ / __ / 20___	__ / __ / 20___	
	Chest wall		__ / __ / 20___	__ / __ / 20___	
	Supraclavicular fossa (SCF)		__ / __ / 20___	__ / __ / 20___	
	Axilla		__ / __ / 20___	__ / __ / 20___	
	Number of radiotherapy fractions, please enter on line _____				
	Total radiotherapy dose please enter on line _____				
Neo-adjuvant chemotherapy	Drug(s), please give details below _____		__ / __ / 20___	__ / __ / 20___	
Chemotherapy	Neo-adjuvant chemotherapy number of cycles, please enter on line _____				
	Drug(s), please give details below _____		__ / __ / 20___	__ / __ / 20___	
	Chemotherapy number of cycles, please enter on line _____				

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
Hormone therapy	Tamoxifen		__ / __ / 20___	__ / __ / 20___	
	Anastrazole		__ / __ / 20___	__ / __ / 20___	
	Letrozole		__ / __ / 20___	__ / __ / 20___	
	Exemestane		__ / __ / 20___	__ / __ / 20___	
	Other, please give details below _____		__ / __ / 20___	__ / __ / 20___	
	Was hormone therapy given with ovarian suppression (please tick) Yes ____ No ____ Unknown ____				
	Was hormone therapy given with bisphosphonates (please tick) Yes ____ No ____ Unknown ____				
Symmeterisation operations	Contralateral prophylactic mastectomy		__ / __ / 20___	__ / __ / 20___	
	Other symmeterisation operation (please give details) _____		__ / __ / 20___	__ / __ / 20___	
Immunotherapy	Trastuzumab (Herceptin)		__ / __ / 20___	__ / __ / 20___	
	Pertuzumab (Perjeta)		__ / __ / 20___	__ / __ / 20___	
	Other immunotherapy (please give details _____		__ / __ / 20___	__ / __ / 20___	

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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 _____

Since the participant's diagnosis of breast 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

Details of participant's new cancer diagnosis

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

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

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

Yes		No	

If the participant has had a recurrence, on what date was the recurrence diagnosed? d d m m y y y y

If the participant has had a recurrence, was the recurrence local or distant? (please tick one box)

Local recurrence	
Distant recurrence	

If the participant has had a recurrence, is any further treatment planned? (please tick one box and if "yes" give details)

Yes		No	

Please describe any planned treatment

_____

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	
Participant has been referred to community services	
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