HORIZONS

UNIVERSITY OF Southampton

Understanding the impact of cancer diagnosis and treatment on everyday life

BASELINE BREAST 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	
Breast	Invasive ductal breast cancer	
	Invasive lobular breast cancer	
	Other (please describe below)	
	Not currently known	

Date of participant's 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 (please add details OR tick the box indicating the TNM stage is not currently known)

T _____ N _____ M _____

TNM not currently known ☐

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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

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

Number 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 pre-treatment 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)	

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

Pre menopause	
Post menopause	
Unknown	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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 boxes 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	

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

Yes		No		Unknown	

If you answered "Yes" 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		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 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	

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 it diagnosed? (Please complete the table overleaf)

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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

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 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	

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

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.)	
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) _____	

What is the participant's proposed treatment start date (main first-line treatment for breast 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 CRF completed

d d / m m / y y y y