



## 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 Coordinating Centre, email address <u>HORIZONS@soton.ac.uk</u>
- 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 weightk	g Participant's height cms	
Participant's blood pressure which they were measured)	e (Please give the most recently reported figures and the	date on
Systolic	mmHg Date measured	
Diastolic	mmHg d d m m y	у у у
Participant's tumour type (p	please tick one box)	
Туре	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)

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)

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)

No

Unknown

If you answered "Yes" to the above question, was the result (please tick one box)

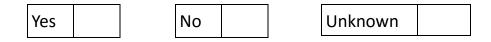
Positive for a mutation in BRCA1 or BRCA2	
Negative for a mutation in BRCA1 or BRCA2	
Ambiguous or uncertain	
Unknown	
Awaiting result	

HORIZONS; Baseline Case Report Form; Breast. Version 3.1, 11/08/2017, IRAS Project ID: 202342, REC reference number 16/NW/0425P

Participant's Study ID	/	1			

Has the participant had any other genetic tests for inherited cancers?

(please tick one box)



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	

HORIZONS; Baseline Case Report Form; Breast. Version 3.1, 11/08/2017, IRAS Project ID: 202342, REC reference number 16/NW/0425P



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

Paralysis (paraplegia or hemiplegia)	
Neuromuscular Condition (multiple sclerosis, Parkinson's, myasthenia gravis, other chron- ic 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, 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 medi- cal complications)	
Morbid Obesity	
Other (please give details)	

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



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

Name \_\_\_\_\_ Signature \_\_\_\_\_ Date CRF completed

