

## How to complete a Screening Log

Within our Site Initiation Visit we have provided you with your Site specific Screening Log and have explained how to fill it in and return it to us. On the Blank Screening Log you will find your Site specific information like Site ID, Site Name and Principal Investigator within the header. Check these are correct, if you need any edits making please email us for an updated electronic version.



### HORIZONS - **Breast Cancer Cohort** – Screening Log

Study short title	HORIZONS study: Understanding the impact of cancer diagnosis and treatment on everyday life	Ethics No.	16/NW/0425
Sponsor	University Hospital Southampton NHS Foundation Trust	Principal Investigator	
Site		Chief Investigator	Prof. Claire Foster
Site ID		Agreed day for faxing	

#### FAX COMPLETED LOG SHEET TO HORIZONS – WEEKLY: 023 8059 7967 or 7951

Log Sheet No:

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort-B; Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted	
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001			
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___	
			Declined any participation	2.	Reason declined:		
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___	
			Missed approaching (eligible)	4.	Reason not approached:		
			Ineligible following screening <sup>§</sup>	5.	Reason ineligible following screening:		
			Any comments:				
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___	
			Declined any participation	2.	Reason declined:		
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___	
			Missed approaching (eligible)	4.	Reason not approached:		
			Ineligible following screening <sup>§</sup>	5.	Reason ineligible following screening:		
			Any comments:				
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___	
			Declined any participation	2.	Reason declined:		
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___	
			Missed approaching (eligible)	4.	Reason not approached:		
			Ineligible following screening <sup>§</sup>	5.	Reason ineligible following screening:		
			Any comments:				

<sup>§</sup> Minimum criteria for screening: new diagnosis of primary breast cancer, clinical stages I – III and awaiting primary treatment with curative intent

**Key Tips:**

- Use XX for the patient initials if they are declined, missed or ineligible
- Use the patients initials for full consent and documents taken home/posted
- All patients screened regardless of their outcome should follow a consecutive numbering system eg 001, 002
- Screening logs numbers should also be consecutive
- Complete the decliners log for any declined patients and return every 3 months if you have screened 5 or more patients.
- When you know the documents taken home/posted outcome update the original screened entry

Please remember to include every potential eligible patient onto the screening log. The screening logs will be faxed to the coordinating centre once a week on an agreed set day. Add the agreed day to the screening log.

When a study participant has been screened by your research team please take the following steps to complete the screening log:

1. **Log Sheet Number:** Enter a Log Sheet No (*This will be the next sequential number every week*)
2. **NHS & Hospital Number:** *Please do not provide us with this information, it is for your reference only!* Please fold this section of the screening log over prior to faxing it through to us.



**HORIZONS - Breast Cancer Cohort – Screening Log**

Study short title	HORIZONS study: Understanding the impact of cancer diagnosis and treatment on everyday life	Ethics No.	16/NW/0425
Sponsor	University Hospital Southampton NHS Foundation Trust	Principal Investigator	
Site		Chief Investigator	Prof. Claire Foster
Site ID		Agreed day for faxing	

**FAX COMPLETED LOG SHEET TO HORIZONS – WEEKLY: 023 8059 7967 or 7951**

**Log Sheet No:**

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=B, Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001		
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___
			Declined any participation	2.	Reason declined:	
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___
			Missed approaching (eligible)	4.	Reason not approached:	
			Ineligible following screening \$	5.	Reason ineligible following screening:	
			Any comments:			

3. Study ID (GYNAE ONLY)



HORIZONS - **Gynaecological Cancer Cohort** – Screening Log

Study short title	HORIZONS study: Understanding the impact of cancer diagnosis and treatment on everyday life	Ethics No.	16/NW/0425
Sponsor	University Hospital Southampton NHS Foundation Trust	Principal Investigator	
Site		Chief Investigator	Prof. Claire Foster
Site ID		Agreed day for faxing	

FAX COMPLETED LOG SHEET TO HORIZONS – 023 8059 7967 or 7951

LOG SHEET NUMBER:

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=C/E/O/V, Consecutive study number BS01C001, LC01E002 etc Please confirm the cancer type	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01C001#		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01V001 #		
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___
			Declined any participation	2.	Reason declined:	
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___
		Cervical = C	Missed approaching (eligible)	4.	Reason not approached:	
		Endometrial = E	Ineligible following screening <sup>§</sup>	5.	Reason ineligible following screening:	
		Ovarian = O	Any comments:			
		Vulval = V				

If your site is recruiting to the gynaecological cohort, you will need to record which specific gynaecological cancer the patient will be treated for – cervical, endometrial or ovarian. Please confirm the specific cancer is known at this stage please select the appropriate type by ticking the selection box within the study ID column.

This will be reflected in the study ID for the cohort.

- Cervical cohort ID = C
- Endometrial cohort ID = E
- Ovarian (or primary peritoneal and fallopian tube) cohort ID = O
- Vulval cohort ID = V

For the other cancer types the screening log lists the relevant cohort ID B=breast and N=NHL and this will be consistent for all patients on the log.

4. **Full Consent:** complete the following sections

- Screening date dd/mm/yy
- Study ID (patients initials – no middle names, site ID, cohort and three digit consecutive number e.g. AB01B001)
- Select outcome 1
- Proposed Tx start dd/mm/yy – enter the proposed start of treatment if known. If not enter NK.
- Fax the consent form and the contact details as soon as possible

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=B, Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001		
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___
			Declined any participation	2.	Reason declined:	
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___
			Missed approaching (eligible)	4.	Reason not approached:	
			Ineligible following screening <sup>5</sup>	5.	Reason ineligible following screening:	
			Any comments:			

5. **Declined any participation:** complete the following sections

- Screening date dd/mm/yy
- Study ID (XX instead of patients initials, site ID, cohort and three digit consecutive number e.g. XX01B001)
- Select outcome 2 and if given state the reason declined. If no reason given state not known.
- Completed the Declined Demographic log as soon as possible and fax back to us every 3 months as long as there are 5 or more patients listed.

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=B, Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001		
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___
			Declined any participation	2.	Reason declined:	
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___
			Missed approaching (eligible)	4.	Reason not approached:	
			Ineligible following screening <sup>5</sup>	5.	Reason ineligible following screening:	
			Any comments:			

6. **Documents taken home/posted. This outcome refers to any consent forms given to the patient to take home with them:** complete the following sections

- Screening date dd/mm/yy
- Study ID (patients initials – no middle names, site ID, cohort and three digit consecutive number e.g. AB01B001)
- Select outcome 3
- Date documents taken home/posted dd/mm/yy.
- Proposed Tx start dd/mm/yy – enter the proposed start of treatment if known. If not enter NK.
- If the patient decides to consent they will post the signed consent form to the coordinating centre and we will forward the original onto the site for a countersignature. Once countersigned fax the consent form to the coordinating centre. The patients consent date and the countersigned consent date will be different but as long as the date the documents are taken home or posted is recorded in the medical notes you will have a suitable audit trail.
- If a few weeks has passed since the treatment date and nothing has been returned we will count the outcome as declined and inform you of the change in outcome.
- Once you have an updated screening outcome for these patients, update the original screening entry with the new screening outcome and cross through and initial the documents taken home/posted outcome.

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=B, Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted	
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001			
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___	
			Declined any participation	2.	Reason declined:		
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___	
			Missed approaching (eligible)	4.	Reason not approached:		
			Ineligible following screening <sup>5</sup>	5.	Reason ineligible following screening:		
			Any comments:				

Please remember to add the study ID to the questionnaire, consent form and contact details form (and the right hand column) before you give or send any documents to patients.

7. **Missed approaching (eligible):** complete the following sections

- Screening date dd/mm/yy
- Study ID (XX instead of patients initials, site ID, cohort and three digit consecutive number e.g. XX01B001)
- Select outcome 4
- Provide a reason for the missed approached

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=B, Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001		
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___
			Declined any participation	2.	Reason declined:	
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___
			Missed approaching (eligible)	4.	Reason not approached:	
			Ineligible following screening <sup>&gt;</sup>	5.	Reason ineligible following screening:	
			Any comments:			

8. **Ineligible following screening:** complete the following sections

- Screening date dd/mm/yy
- Study ID (XX instead of patients initials, site ID, cohort and three digit consecutive number e.g. XX01B001)
- Select outcome 5
- Provide a reason for the ineligibility following screening

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=B, Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001		
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___
			Declined any participation	2.	Reason declined:	
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___
			Missed approaching (eligible)	4.	Reason not approached:	
			Ineligible following screening <sup>&gt;</sup>	5.	Reason ineligible following screening:	
			Any comments:			

### 9. Any comments

This section is available for any additional comments. If you have screened a patient but do not yet have an outcome for example you are due to approach the patient in clinic in the next week, use this comments box to explain.

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date dd/mm/yy	Study ID; Pt initials, site ID, cohort=B, Consecutive study number BS01B001, LC01B002 etc	Outcome:	1. Full Consent / 3. Documents taken home/posted: Study ID include initials eg: BS01B001		Proposed treatment start date 1. Full consent/ 3. Documents taken home/posted
				2. Declined / 4. Missed Approach/ 5. Ineligible following screening: XX instead of initials eg: XX01B001		
			Full consent	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___
			Declined any participation	2.	Reason declined:	
			Documents taken home/posted	3.	Date taken home/posted ___/___/___	Proposed Tx start ___/___/___
			Missed approaching (eligible)	4.	Reason not approached:	
			Ineligible following screening <sup>5</sup>	5.	Reason ineligible following screening:	
			Any comments:			

10. A key tips box is located at the bottom of the screening log to help aid in the screening log completion.

**Key Tips:**

- Use XX for the patient initials if they are declined, missed or ineligible
- Use the patients initials for full consent and documents taken home/posted
- All patients screened regardless of their outcome should follow a consecutive numbering system eg 001, 002
- Screening logs numbers should also be consecutive
- Complete the decliners log for any declined patients and return every 3 months if you have screened 5 or more patients.
- When you know the documents taken home/posted outcome update the original screened entry

If you have any questions regarding the screening log completion please email [HORIZONS@soton.ac.uk](mailto:HORIZONS@soton.ac.uk) or ring 02380 595 294.