

How to complete a Decliners Log

1. Why do we need Decliners Logs

The Decliners Logs are designed to collect anonymous, aggregate data on patients who are eligible for HORIZONS but who decline the study.

We are collecting:

- Gender (for the NHL cohort)
- Age in years
- Stage of disease
- ECOG Performance Status

By collecting this data, we will be able to compare decliners and consenters and see if there are any biases. For example, we might find that decliners are, on average, older than consenters, or that decliners tend to have a poorer Performance Status than consenters.

It is extremely important for the science of the HORIZONS study that we are able to compare decliners and consenters.

There are Decliners Logs for each cohort: Breast; Gynae and NHL. The current versions of the Decliners Logs are version 2.0. Please use the Decliners Log individualised to your site (with a site ID number and a site name)

2. Completing the Breast and Gynae Decliners Logs

Below is a screen shot of the Breast Decliners Log. The Decliners Logs can be completed on paper or electronically. Please make an entry in the Decliners Log for every patient who declines to take part in HORIZONS. The patient does not need to be present for this.

Please enter the following on the log:

1. Log Sheet No. - Enter the consecutive log sheet number ie 1,2,3,4 etc.
2. Study ID – Enter the patient’s HORIZONS study ID. This will begin XX. You are entering the study ID to keep track of decliners at your site and ensure every decliner has been entered on the Log. The HORIZONS team do not need this information. Please cover/delete before returning your Log sheet

3. Age – Enter the patient’s age in years
4. Cancer number stage – Place a mark in one column, either Stage 1, Stage 2 or Stage 3 corresponding to the patient’s cancer number stage
5. ECOG Performance Status – Place a mark in one column, either ECOG 0, ECOG 1, ECOG 2, ECOG 3 or ECOG 4 corresponding to the patient’s performance status. The marks can be grouped in a tally system as shown below:

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6. Totals – Please enter the column totals for each cancer number stage and each ECOG Performance Status

3. Completing the NHL Decliners Log

The NHL Decliners Log is slightly different, it asks for the decliner's gender as well as age, stage and ECOG status.

To complete the NHL Decliners Log, follow the instructions for the Breast Decliners Log, in addition place a mark in one column, either Male or Female corresponding to the participant's gender.



HORIZONS – Decliners Log - NHL

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			

SEND COMPLETED LOG SHEET TO HORIZONS – EVERY 3 MONTHS: By fax to: 023 8059 7967 or 7951; by email to bjoern.schukowsky@nhs.net

Log Sheet No:

1. **Study IDs and ages.** Please enter the study ID and the age (in years) of each decliner in the table overleaf.
2. **Non-identifiable tally of gender and ECOG Performance Status.** For each decliner, please place a tick in one of the gender columns, one of the cancer stage columns and one of the ECOG Performance Status columns.

Study ID (taken from the Screening Log) <i>CONCEAL prior to faxing or emailing</i>	Age (years)	TALLY OF GENDER (place a tick in the appropriate column for each decliner)		TALLY OF cancer number stage (place a tick in the appropriate column for each decliner)				TALLY OF ECOG PERFORMANCE STATUS (place a tick in the appropriate column for each decliner)				
		MALE	FEMALE	Stage 1	Stage 2	Stage 3	Stage 4	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)
		Total=	Total=	Total=	Total=	Total=	Total=	Total=	Total=	Total=	Total=	Total=

4. When to start using the V2.0 Decliners Logs

If you have entered decliners on an old (V1.1) Decliners Log but have not sent it to us, please continue to use that Log until there are at least 5 people on the Log and you receive a request from us to return it. After, that please start using the new (V2.0) Logs.

5. Returning the Decliners Logs

Please return Decliners Logs to the HORIZONS study team in Southampton every 3 months, either by email or by fax. We will remind you when the Decliners Logs are nearly due. Decliners Logs should only be returned to us if 5 or more patients are entered on the Log. If there are less than 5 patients on the Log, you can continue to use the Log over the next 3 month period, just let us know when we send the reminder request for

After sending a completed Decliners Log, please start a new Decliners Log and mark it with the next Log sheet number.

4. Return of the Decliners Logs

Decliners Logs should be returned by fax or as an email attachment

Emails should be sent to our nhs.net account: Bjoern.Schukowsky@nhs.net and password protected where possible.

The HORIZONS co-ordinating centre will send a request for your Decliners Log every three months

If there are fewer than five patients on the Decliners Log, there is no need to return it – continue using it for the next three month period

Thank you – if you have any questions, please email us: HORIZONS@soton.ac.uk