

Study-Specific SOP

MiSTY Study Laboratory Research SOP

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT
THE CORRECT VERSION IS BEING USED**

Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise.

If you are reading this in printed form check that the version number and date below is the most recent one.

SOP Reference:	R&D/S1 MiSTY Study
Version Number:	1.0
Author:	Ella Banken
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Approved by:	Name/Position:	Marthe Ludtmann, Lab Manager
	Date:	24 th February 2026
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	24 th February 2026

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	24 th February 2026	Ella Banken	New SOP created

UNCONTROLLED DOCUMENT WHEN PRINTED

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1 Introduction, Background and Purpose

Full study title: **Measuring Icterus from Sclera Tinge Yellowness (MiSTY)**

Local Project Reference: **344432Y&S**

Principal Investigator: **Georgia Sowerby (University of York), Dr Ol' Tunde Ashaolu**

Recruitment Target: **100 participants**

Site: **York and Scarborough**

Sponsor: **The University of York**

Study objectives:

Primary study objective: To determine whether images of the eyes can be used to develop a reliable, non-invasive method for categorising the severity of jaundice.

Secondary study objective: To assess how accurately the developed non-invasive method can categorise different levels of jaundice severity compared to traditional blood tests, and to determine the minimum serum bilirubin level it can reliably detect using eye images.

Purpose:

This study will be using bilirubin test results taken as standard of care to select and subsequently approach study participants. This SOP describes the process for retrieving the relevant data, formatting it and forwarding it to the relevant research delivery teams.

2 Who Should Use This SOP

Research and Innovation Laboratory staff ("R&I Labs") who have a valid Good Clinical Practice (GCP) training certificate, and up-to-date Research CV and who have signed on to the Study Delegation and Signature Log.

3 When this SOP Should be Used

This SOP should be followed when retrieving, formatting and forwarding patient data relevant to the study.

4 Procedure(s)

4.1 Retrieving patient data

4.1.1 Data search

Standard of care test result data stored on Winpath, the Laboratory Information Management System (LIMS), can only be retrieved by members of the Pathology IT team through the PathManager application.

A search has been set up to retrieve and output the following information:

- Requesting site (York or Scarborough)
- NHS number
- Patient name
- Date of birth
- Age
- Date and time of specimen taken
- Date and time of specimen received
- Transit time (hours)
- Test description (Bilirubin)
- Numeric result (in $\mu\text{mol/L}$)

4.1.2 Contacting Pathology IT

The main contact for running the search and retrieving study data is **Lincy Jose (Pathology IT Systems Specialist)** at lincy.jose@nhs.net

Alternative contacts are:

Shared inbox: yhs-tr.shypspathologyit@nhs.net

Matthew Spencer: matthew.spencer15@nhs.net

Thomas Lang: thomas.lang1@nhs.net

Pathology IT will ideally need to be notified in advance of the study days on which data is to be received. These are likely to be Monday through Thursday in York and Tuesday through Thursday in Scarborough. Data will initially be sent once daily on those study days, ideally at 09:00, though there might be a possibility later on during the study to obtain data twice daily. The above contacts can be used to notify Pathology IT of data being required or to chase up requested data.

Data should be requested for samples **taken** within the last 48 hours prior to request made.

4.2 Formatting and sending patient data

The data received from Pathology IT will contain all the required information; however it will need to be formatted correctly and any unusable information removed before sending to the relevant research delivery team.

4.2.1 Saving data received from Pathology IT

1. Save the received data (should be in Excel format) to the MiSTY 07. *Pathology Data* folder, in the correct month subfolder, naming the file '*Bilirubin_DDMMYYYY*'.
2. Open the file you have just saved in Microsoft Excel.

3. Select the top left corner of the data (on the header) and hold 'ctrl' and 'T'. Ensure 'My table has headers' is selected and click 'OK' to make a table.
4. Filter the data by location – York or Scarborough.
5. Filter the data in the 'Date & Time of Specimen' column to include only samples collected within the **last 48 hours**. This can be done by ticking or unticking the appropriate dates and times in the filtering drop-down menu.
6. On the first study day of the week (Monday in York, Tuesday in Scarborough), data for the last 48 hours will be shared with the research delivery team. Move on directly to step 8 from here.
7. On any other study day that is not the first study day of that week, only new results which have been generated since the last Pathology IT data was shared the previous day, will be included. This is to avoid duplication when sending results to the research delivery team. To filter these results, carry out the following steps:
 - Open the '*Bilirubin_DDMMYYYY*' file from the previous day.
 - In this file from the previous day, filter the 'Date & Time of Receipt' column from newest to oldest, and make a note of when the most recent sample was received.
 - In the **current** day '*Bilirubin_DDMMYYYY*' file, filter the data in the 'Date & Time of Receipt' column to remove any timepoints prior to the time at which the most recent sample was received the previous day.
 - This process should ensure that duplication from one day to another is removed.
8. In the 'Age' column, filter data by removing any patients younger than 18.
9. Filter the bilirubin results ('Numeric Result' column) from smallest to largest.
10. Save the Excel workbook.

4.2.2 Creating patient lists to send to the research delivery team

1. Navigate to the MiSTY 08. *Formatted Patient Lists* folder, in the *Templates* subfolder, open the '*Normal_bilirubin_patient_list_TEMPLATE*' file in Excel.
2. Save this file as a new Excel workbook in the relevant month of the MiSTY 08. *Formatted Patient Lists* folder following the format '*Normal_bilirubin_patient_list_DDMMYYYY*'.
3. Copy all the top bilirubin results from the formatted *Bilirubin_DDMMYYYY* table that have a bilirubin result **less than 21µmol/L** and paste these into the '*Normal_bilirubin_patient_list_DDMMYYYY*' file, making sure to paste values only. Ignore any rows without bilirubin values.
4. The template will highlight any patients without NHS number, delete these rows.

5. Delete the columns 'Date & time received' and 'Transit time (hours)' as the research delivery team does not need these.
6. The template will also highlight any duplicate NHS numbers and names, keep the row with the most recent bilirubin result and delete the other rows. In the 'Date & time taken' column, sort results from newest to oldest to help with this. Once the duplicate names are removed, the cells will no longer be highlighted.
7. Save the Excel workbook.
8. Navigate to the MiSTY 08. *Formatted Patient Lists* folder, in the *Templates* subfolder, open the '*Elevated_bilirubin_patient_list_TEMPLATE*' file.
9. Save this file as a new Excel workbook in the relevant month of the MiSTY 08. *Formatted Patient Lists* folder following the format '*Elevated_bilirubin_patient_list_DDMMYYYY*'.
10. Copy the bilirubin results from the formatted *Bilirubin_DDMMYYYY*' table that have a bilirubin result **greater than or equal to 21µmol/L** and paste these into the '*Elevated_bilirubin_patient_list_DDMMYYYY*' file, making sure to paste values only. Ignore any rows without bilirubin values.
11. The template will highlight any patients without NHS number, delete these rows.
12. Delete the columns 'Date & time received' and 'Transit time (hours)' as the research delivery team does not need these.
13. The template will also highlight any duplicate NHS numbers and names, keep the row with the most recent bilirubin result and delete the other rows. In the 'Date & time taken' column, sort results from newest to oldest to help with this. Once the duplicate names are removed, the cells will no longer be highlighted.
14. Save the Excel workbook.
15. Send a copy of both workbooks (normal and elevated results) to the relevant research delivery team, aiming to send these at 09:30 on each study day.

5 Related SOPs and Documents

N/A