STANDARD OPERATING PROCEDURE

NIHRexe291STARTRIGHT – StartRight Study – Visit 4 – Data and Sample Collection/Processing for On-Site and Remote Participant Visits

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Date	15 June 2021

Controlled document

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It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please check the study website (https://www.diabetesgenes.org/current-research/startright/startright-professionals/) or contact the central coordinating team (rde-tr.DiabetesResearch@nhs.net) to confirm you have the latest version.

DISCLAIMER

This study specific Standard Operating Procedure (SOP) must be followed unless a departmental SOP dictates a different working practice.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author(s)**	**Reason**
1.0	19 Aug 2019	Anita Hill & Peter Tippett	Initial version
2.0	25 May 2021	Anita Hill	Updated to cover both on-site and remote visits
2.1	15 June 2021	Anita Hill	Minor update to section 6.1 to clarify timing of visit

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1 INTRODUCTION

It is not always easy for doctors to be able to say for certain what kind of diabetes a person has (particularly in adults aged under 50), where the distinction between the types is less clear. Getting the right diagnosis is important to know what treatment will be most effective; for example patients with Type 1 diabetes need insulin, whereas most patients with type 2 diabetes may be effectively treated without insulin.

The purpose of this research is to determine whether blood tests can help us improve treatment by identifying which patients have Type 1 diabetes, and will need very early insulin treatment, and which patients are unlikely to need insulin treatment at diagnosis. These tests include antibodies against the cells that make insulin (often seen in Type 1 diabetes), and a new test which assesses genetic risk of diabetes.

2. PURPOSE

The purpose of this SOP is to ensure correct and uniform data & sample collection from participants in the StartRight study.

3. SCOPE

This SOP applies to all individuals involved in the follow-up of participants recruited to the StartRight study.

4. DEFINITIONS

CI	Chief Investigator
PI	Principal Investigator
DCF	Data Collection Form
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigator Site File
R&D	Research & Development
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
TMF	Trial Master File

5. DUTIES AND RESPONSIBILITIES OF STAFF

All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

This procedure should only be carried out by personnel who have undergone appropriate trust, GCP, and study specific training.

This procedure should only be carried out by personnel who are appropriately listed on the study specific delegation log, signed off by their PI, in their ISF.

All staff should be aware that local Trust policies and procedures apply when planning and undertaking studies.

The SOP will be circulated to all StartRight study teams shortly after release and will be uploaded to the study website https://www.diabetesgenes.org/current-research/startright/

6. PROCEDURES (for summary flow diagram of procedures please see appendix D)

6.1 *Timing of follow-up appointment* & initial contact with participant

6.1.1 As detailed in the study Protocol (item 5.1.6), Visit 4 will be conducted at least 3 years from participant's diabetes diagnosis.

6.1.2 A pre-calculated list of follow-up dates from study participants will be provided to each recruiting site in the format:

Study ID	**Earliest Visit 4 Date (3 years after diagnosis)**	**Date Visit 4 completed**	Retake DNA *
SRXXXX	dd/mm/yyyy	*Local study team to update on completion of visit 4*	Yes/No

* *Only where DNA was not collected at Visit 1. For participants requiring DNA samples to be retaken, appropriate collection packs will be supplied.*

6.1.3. Using the most recent contact details for the participant (recorded at Visit 1 and updated at subsequent follow up) and contact preferences, attempt to make contact with the study participant, by phone or email, as close to (but not prior to) their earliest Visit 4 date. This will help to ensure that, if there are any delays/difficulties in making contact, a successful contact is made in the required time period

6.1.4. Clearly record all attempts to make contact with the participant in the space provided on the back of the participant referral and contact form.

6.1.5. When contact is made with the participant, review the details of the study (as per the current PIS) and re-confirm consent with the participant.

6.1.6. Ensure the participant is given the opportunity to ask any questions, and that they are happy to proceed with study follow-up.

6.1.7. Check that the contact details recorded at visit 1 and visit 2 are still current and record any changes on page 1 of the visit 4 DCF.

6.1.8. Check that the participant's GP, is as recorded at previous visit(s), and record any changes on the visit 4 DCF.

6.1.9 **AGREE FACE TO FACE OR REMOTE VISIT WITH PARTICIPANT:** Face to face visits with venous blood collection are preferable for the study but, depending on local COVID19 policy, may not be possible at all sites. Some participants may not wish to attend an on-site appointment for reasons of convenience or COVID security.

6.1.10 **For both on-site & remote visits**: Book a convenient date and time with the participant to either, visit the local research centre, or to speak with a researcher on the phone to go through data collection and the remote blood collection process.
IMPORTANT NOTES:
**** For Remote Visits, please allow at least 7 working days for the sample collection pack to be sent to the participant from the central team in Exeter.***

**** For On Site Visits, please try to avoid booking appointments on Thursday afternoon or on a Friday to ensure that samples do not arrive in Exeter at the weekend.***
**** For All Visits: Book at any convenient time during the day but participants must have consumed a meal containing carbohydrate within the previous 1 to 5 hours***.

Record the agreed date, time and visit type on page 1 of the DCF.

6.1.11 **FOR REMOTE VISITS:** PLEASE CONFIRM PARTICIPANT'S CONTACT DETAILS AND RECORD ANY CHANGES ON PAGE 1 OF THE DCF. SCAN PAGE 1 OF THE DCF TO THE CENTRAL TEAM IN EXETER (rde-tr.DiabetesResearch@nhs.net) AT LEAST 7 WORKING DAYS BEFORE THE AGREED VISIT DATE. THE CENTRAL TEAM WILL ARRANGE DELIVERY OF THE REMOTE STUDY PACK.

6.2 ***Prior to the Study Visit***

6.2.1. Update the participants 'Planned Visit 4 Date' and 'Planned Visit 4 Time' on CRF Tracker. (See Appendix B).

6.2.2 **FOR ON-SITE VISITS ONLY:**
Confirm the details of the agreed appointment for Visit 4 by email or letter in accordance with participant preference.

Assign a Visit 4 study barcode set to the participant. Study documents may be labelled with the appropriate barcode labels in advance of the participant visit but it is best to label research tubes and biochemistry forms with the barcode labels at the time of the appointment.

FOR ON-SITE VISITS, PLEASE CONTINUE TO NEXT SECTION (6.3) BELOW

FOR REMOTE VISITS, PLEASE GO TO SECTION 6.11 on page 10

6.3 Documents & *Equipment*

6.3.1 **Completed documents from previous study visit(s):**

- Participant Referral and Contact Form
- Consent Form
- DCF(s)

Appropriate IT equipment to scan and email completed study documents to the CI site in Exeter by secure nhs.net email account.

6.3.2 **Current versions of the following StartRight study visit 4 specific documents** (please refer to the document list in your ISF for current version number and date).

- StartRight Visit 4 DCF

6.3.3 **Anthropometry equipment:**

- Calibrated class 3 weighing scales
- Stadiometer
- Blood pressure machine

- Tape measure suitable for Waist and Hips

Please see local policies for acceptable equipment at your site.

6.3.4 **StartRight Study Visit 4 – Follow Up Barcode Set: *SR-14-XXXX***

6.3.5 **Visit 4 Blood Sample Collection pack comprising:**

- 1x Postage-paid Jiffy bag
- 1x MTO Lab Instruction form
- 1x Exeter Biochemistry form listing Glycated Hb and Cpeptide
- 1x Sealable plastic bag
- 1x 6.0ml K2E (EDTA) BD Vacutainer
- 1x Elkay tube with blue cap
- 1x 8.5ml SST II *Advance* BD Vacutainer
- 1x 3.0ml K2E BD Vacutainer
- 1x BD Vacutainer Safety-Lok Blood Collection Set with Pre-Attached Holder
- 1x 2.5ml Pasteur Pipette
- 1x Absorbent pouch (3 pockets)

6.3.6 **Standard local venipuncture equipment and following local tube:**

- 1x 2.7ml Fluoride tube for Glucose analysis at local lab

6.3.7 **Visit 4 Urine Sample Collection pack containing:**

- 1x Postage-paid Jiffy bag
- 1x Exeter Biochemistry form listing UCPCR
- 1x Sealable plastic bag
- 1x Home Urine Instruction Form
- 1x Urine Boric Acid container
- 1x Absorbent tissue

6.3.8 **Questionnaires** (for participants to complete at the end of their visit)

- StartRight Visit 4 Hypo Questionnaire
- StartRight Visit 4 Quality of Life SF12 and CD10

6.3.9 **Centrifuge**
Please refer to Appendix A on page 11 for required Centrifuge settings.

6.4 *Prior to Data and Sample Collection*

6.4.1 **Confirm that the participant has eaten a meal containing carbohydrate within the last 1 to 5 hours.**

If the participant is insulin treated, please ask them to check capillary blood glucose before you collect blood samples. Hypoglycaemia will make C-peptide results invalid. Therefore if the participants capillary blood glucose is below 4.0mmol/L, please ask the participant to treat hypoglycaemia as they normally would, and then follow the instructions in point 6.4.2 below.

If the participant has already tested capillary glucose within 1 hour of the visit, and this is >8mmol/L, no repeat is required.

6.4.2 **If the participant has not eaten or has Hypoglycaemia, the options are as follows:**

a) If the participant is happy to stay for a further hour; offer a carbohydrate meal (e.g. toast), record the details of the meal, and time consumed, in the relevant section of the DCF and collect the blood samples after 1 hour.

b) If the participant cannot wait for a further hour; please arrange another appointment for blood collection.

6.5 *Data Collection*

6.5.1 Please ensure you use the current version of the Visit 4 DCF which will be pre-filled with your 4 digit site ID.

6.5.2 Label DCF with the appropriate barcode label (**on site visits only**) and add the participants Study ID on every page where indicated (**both visit types**)

6.5.3 The DCF is designed in 'Teleform', meaning the data will be scanned and transferred electronically. The scanning process is extremely sensitive so please write as clearly as possible and keep within the boxes provided.

6.5.4 Please answer **ALL** questions. If data is unavailable, please answer N/A in the relevant field.

6.5.5 Any additional information and/or comments about the visit from researcher or participant should be recorded in the comments box on page 6.

6.5.6 If any errors are made when completing the paperwork, cross through the incorrect answer with a single line and complete the correct answer. Initial and date any amendments.

6.5.7 Following the study visit, collect required historic biochemistry results from the participant's patient records (hospital and/or GP).

6.6 *Blood Sample Collection (On Site Visits)*

6.6.1 Ensure participant is relaxed and comfortable, either sitting in a chair or supine on a bed, depending on their preference.

6.6.2 Explain the procedure fully to the participant.

6.6.3 Following local venepuncture guidelines, collect the following blood samples in the priority order listed below:

1. Research Plasma - 6.0ml K2E (EDTA) BD Vacutainer
2. Research Serum - 8.5ml SST II *Advance* BD Vacutainer
3. Research HbA1c - 3.0ml K2E BD Vacutainer
4. Local Fluoride tube for local glucose analysis

Remove needle, ensuring puncture site is covered and participant is comfortable.

6.7 *Research Blood Sample Processing*

6.7.1 Please follow the detailed instructions in:

- Appendix A – Generic Guidance for Sample Processing
- Appendix B – Sample Processing and Labelling Table
- Appendix C – CRF Tracker Sample Logging Instructions
- Appendix E – Examples of completed Blood and Urine Biochemistry forms

6.7.2 When writing the participant name and date of birth on the tube labels, take care not to write over the 2D barcode on the right hand side of the label. (Fine permanent marker pens are provided for writing on the study labels). First Initial and Surname is acceptable if there is insufficient space to fit full name (e.g. J. Harrison-Potter).

6.7.3 Samples must be in the post on the day of collection to ensure that they arrive at the CI site in Exeter no later than 48 hours after collection.

6.8 *Local Blood Processing and Results*

6.8.1 Send local Fluoride tube for Glucose analysis in accordance with local site protocol

6.9 *Urine Sample Collection*

Check that the participant is happy to provide another urine sample, **preferably at the study visit** OR, if preferred, they may collect at home and send direct to Exeter as per their previous visits.

Prepare a urine sample collection pack as follows:

- Label the Exeter biochemistry form with the participant's details (name, NHS number & date of birth) and the '2hr home urine' biochemistry form barcode label. NOTE: *An example of a completed and labeled form is provided at the end of this SOP.*
- Label the urine collection tube with the participant's name, date of birth and the '2hr home urine' primary tube label.
- If urine is collected at research visit, add date and time of sample collection to the Exeter biochemistry form and dispatch to Exeter in the pack provided.
- If participant is to collect urine sample at home, please go through the home urine collection instructions provided

6.10 *Questionnaires*

If participant has previously consented to complete the Hypoglycaemia and Quality of Life SF12 and CD10 questionnaires, provide them with the questionnaires and ask them to complete them as independently as possible. Label the completed questionnaires with the appropriate labels from the allocated barcode set and add study ID on every page where indicated.

PLEASE GO TO SECTION 6.14 ON PAGE 11 FOR GUIDANCE ON TRANSFER OF DOCUMENTS TO THE LEAD SITE IN EXETER

6.11 REMOTE VISITS

Prior to Remote Data and Sample Collection

6.11.1 Confirm that the participant has received their study pack and confirm the sample collection procedure with them.

6.11.2 **Confirm that the participant has eaten a meal containing carbohydrate within the last 1 to 5 hours.**

If the participant is insulin treated, please ask them to check capillary blood glucose before you collect blood samples.

Hypoglycaemia will make C-peptide results invalid. Therefore, if the participants capillary blood glucose is below 4.0mmol/L, please ask the participant to treat hypoglycaemia as they normally would, and then follow the instructions in point 6.11.3 below.

If the participant has already tested capillary glucose within 1 hour of the visit, and this is >8mmol/L, no repeat is required.

6.11.3 If the participant has not eaten or has Hypoglycaemia, the options are as follows:

a) If it is convenient to collect the samples later the same day, advise the participant to eat a carbohydrate meal (e.g. toast) and arrange to call them again between 1 and 5 hours after they have eaten. Record the details of the meal, and time consumed, in the relevant section of the DCF and collect the blood samples after 1 hour.

b) If sample collection is not convenient later in the day, please arrange another appointment for blood collection.

6.12 Remote *Data Collection*

6.12.1 Please ensure you use the current version of the Visit 4 DCF, which will be pre-filled with your 4 digit site ID.

6.12.2 Add the participants Study ID on every page where indicated (*Note: no barcode label for remote visits)*

6.12.3 The DCF is designed in 'Teleform', meaning the data will be scanned and transferred electronically. The scanning process is extremely sensitive so please write as clearly as possible and keep within the boxes provided.

6.12.4 Please answer **ALL** questions. If data is unavailable, please answer N/A in the relevant field.

6.12.5 If any errors are made when completing the paperwork, cross through the incorrect answer with a single line and complete the correct answer. Initial and date any amendments.

6.12.6 Following the study visit, collect required historic biochemistry results from the participant's patient records (hospital and/or GP).

6.13 Remote Sample Collection

Ask participan to collect the finger prick sample while you are on the phone to support them or arrange to call them back in 10 to 15 minutes to confirm that the samples have been collected and the arrangements for labelling and posting.

Ensure the meal information is completed on page 2 of the DCF and also add the date and time of finger prick blood collection once sample collection is complete.

Full instructions will be provided in the participant's study pack & copies provided to the local research teams. In summary the sample collection procedures are as follows:

- Collect the finger prick and urine samples between 1 hour and 5 hours after you have eaten a meal containing a carbohydrate (e.g. bread, cereal, crackers, potatoes, rice, pasta, noodles, biscuits etc.).
- Finger Prick – Write the date and time of sample collection on the form provided with the sample collection kit. If participant routinely checks finger prick glucose, record the glucose result on the form as well.
- Urine - Write the date and time of sample collection on both the tube and the form.
- Post the samples and all accompanying forms on the day of collection (or the next morning if taken in the evening) as it must reach Exeter within 3 days of collection.
- Complete the Hypoglycaemia and Quality of Life, SF12 and CD10, questionnaires and post them to the Exeter team in the pre-paid envelope provided.

6.14 *Transferring Data to Exeter for Processing* (ALL VISITS)

6.14.1 Ensure that all fields on the data collection form (DCF) have been completed and that all required biochemistry results (including requested historical results) have been recorded.

6.14.2 Ensure that the DCF and Questionnaires have the correct barcode labels and the participants study ID is written on every page where indicated.

6.14.3 Send scanned copies (in PDF format) of the following documents to the StartRight Central Coordinating Team by secure NHS email at:

rde-tr.DiabetesResearch@nhs.net

- Visit 4 DCF
- Visit 4 Hypoglycaemia Questionnaire (when completed on site)
- Visit 4 Quality of Life SF12 Questionnaire (when completed on site)
- Local Glucose Result (on site visits only - in electronic format)

PLEASE SEND ALL DOCUMENTS TO THE CI SITE IN EXETER WITHIN 10 WORKING DAYS OF THE STUDY VISIT

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated study documents will be uploaded to the project website shortly after having been released:

https://www.diabetesgenes.org/current-research/startright/startright-professionals/

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

APPENDIX A: IMPORTANT GENERIC GUIDANCE FOR SAMPLE PROCESSING

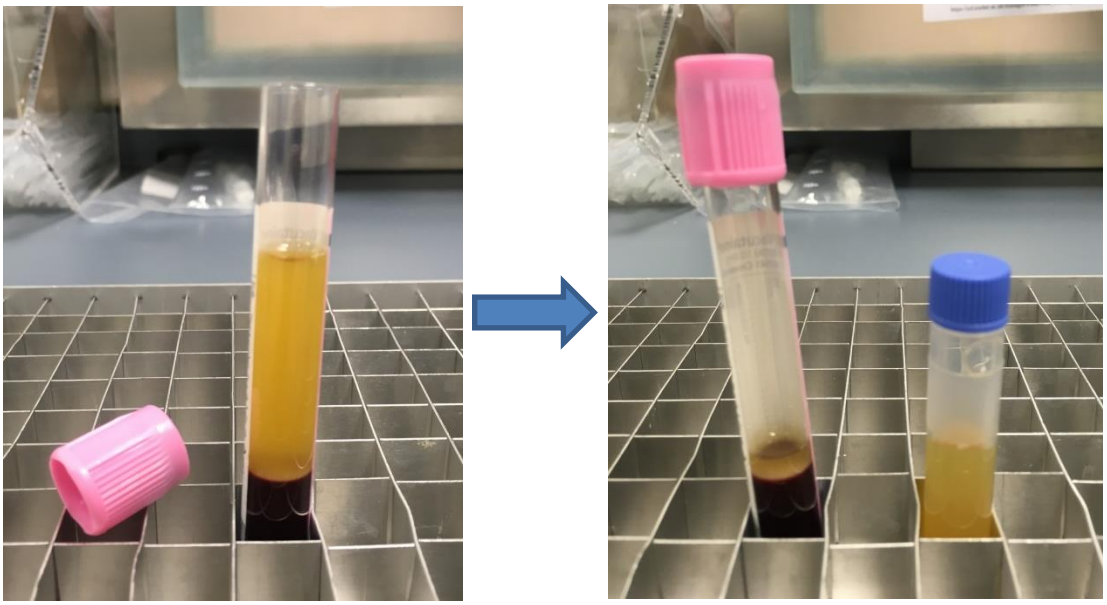
Time from Patient to Centrifuge: The gold standard is to have samples centrifuged within 30 minutes of being taken from the patient. In situations where community visits are necessary, samples must be processed in the shortest time possible, and within 6 hours of being taken from the participant.

Centrifuge Conditions: Please ensure that you have your centrifuge set at the correct RCF in units of times gravity ($x\ g$) to 1300g. For centrifuges that can only be set to RPM the required speed will differ between individual rotors, and will need to be calculated based on the 1300g requirement. If you are not familiar with this, please see the manufacturer's instructions for your centrifuge and/or discuss with a laboratory technician. If your centrifuge has a temperature setting, please set to 20˚C.

Serum Samples: Please ensure that Serum tubes (SST II *Advance* BD Vacutainers) are well mixed and allowed to clot in an upright position prior to centrifugation.

Centrifugation Time: Centrifuge the Plasma and Serum tubes for 10 minutes.

Plasma Separation: When pipetting the plasma supernatant, be very careful not to take the white cells (buffy coat) on top of the layer of red cells.



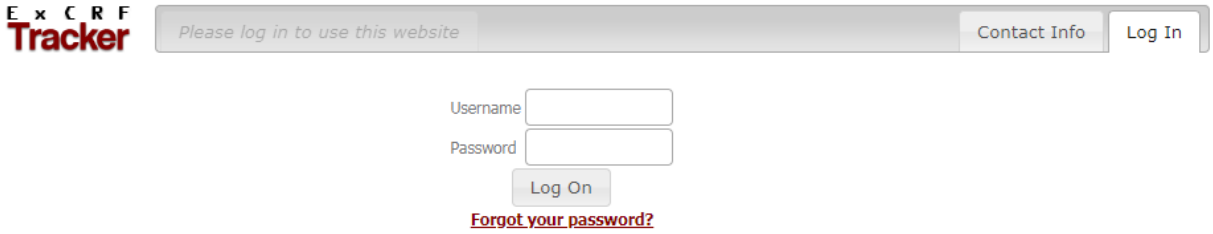
SAMPLES MUST BE DISPATCHED ON THE DAY OF COLLECTION TO ENSURE THAT THEY ARRIVE AT THE CI SITE IN EXETER PREFERABLY BY THE NEXT DAY, BUT NO LATER THAN 48 HOURS AFTER COLLECTION.

APPENDIX B: CRF TRACKER INSTRUCTIONS

Please use the instructions below to add visit 4 dates and log study samples into CRF Tracker.

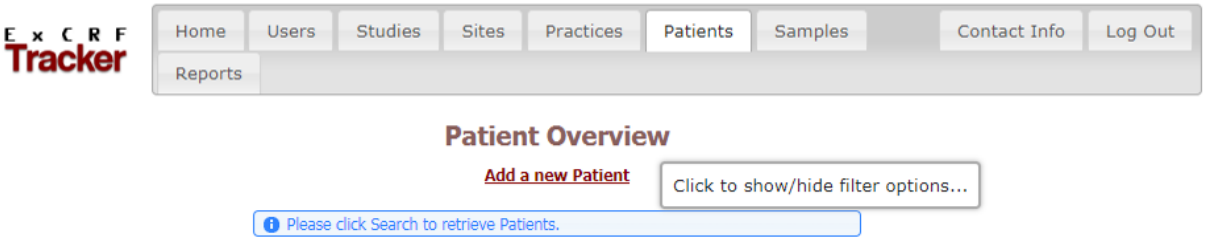
OPENING CRF TRACKER

- To open CRF Tracker, enter the following URL into the Google Chrome internet browser: https://ctu-live.exeter.ac.uk/tracker/Default.aspx
- Log in with your personal username and password assigned to you by the CI site in Exeter.

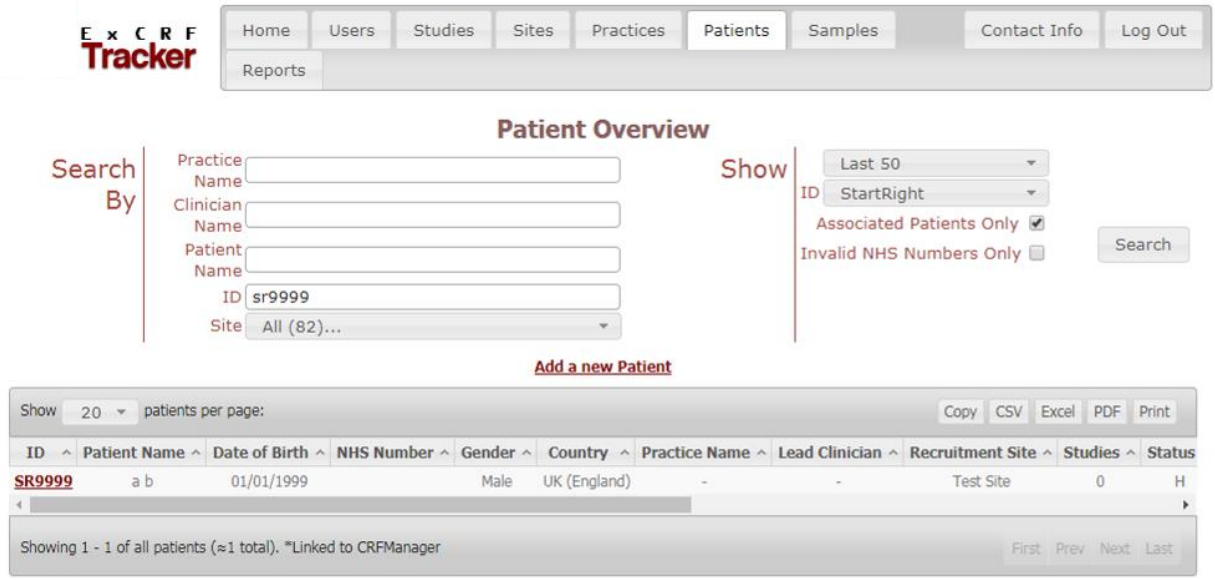


ADDING A PLANNED VISIT 4 DATE AND TIME

1. Once logged in to CRF Tracker, select the '**Patients**' tab.

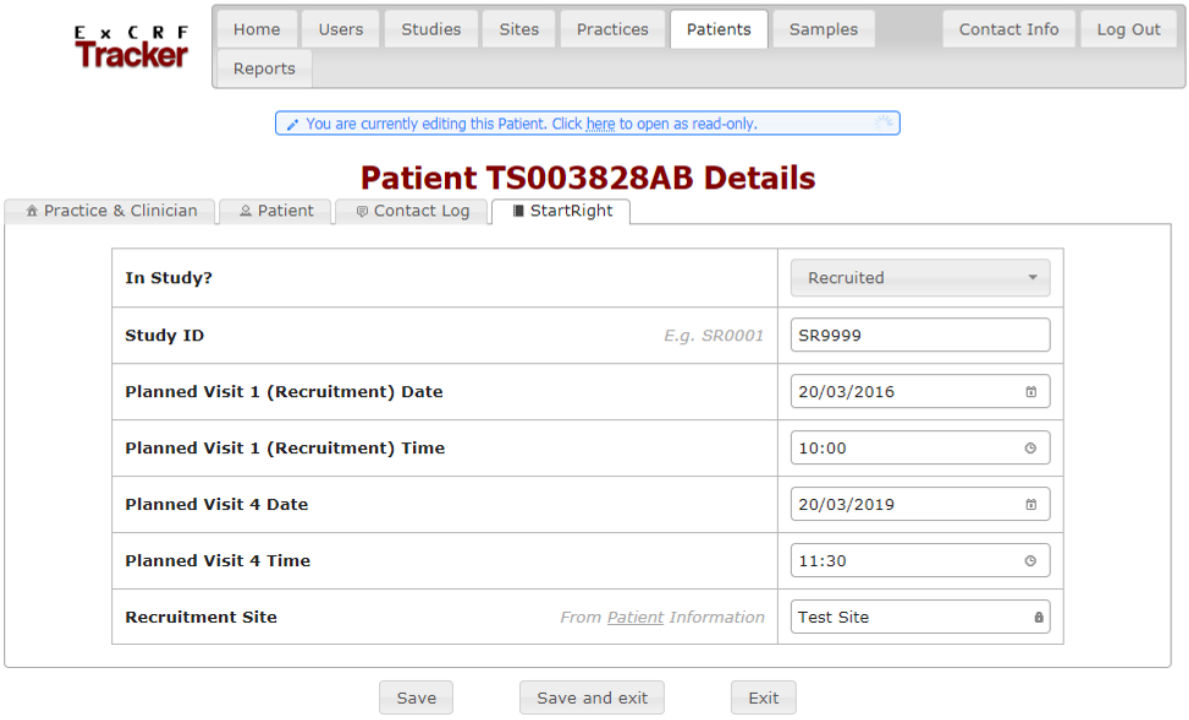


2. Click on '**Patient Overview**' to show the search option.
3. Type the participant's Study ID into the '**ID**' search field, and click search.



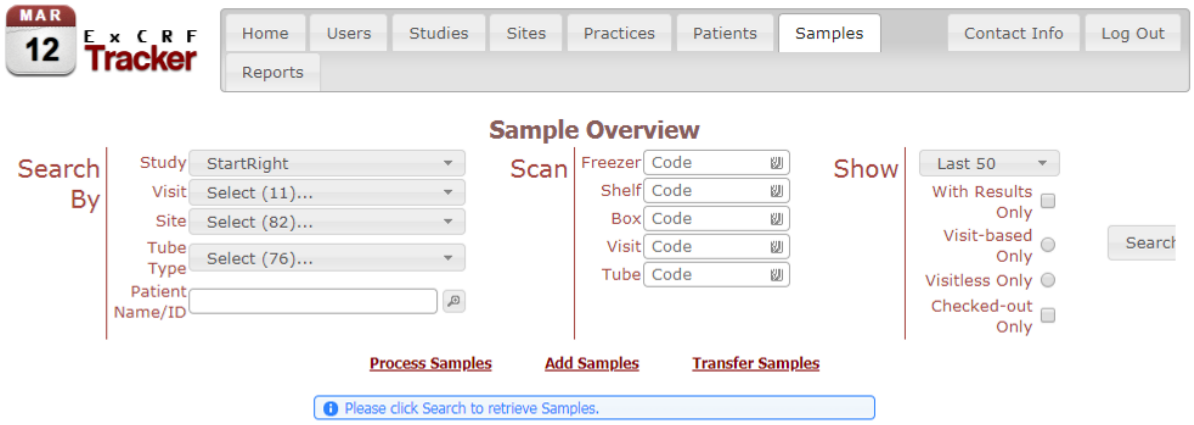
4. Click on the underlined '**ID**' in the search results to open the participant details.

5. Select the '**StartRight**' tab, and enter the participants '**Planned Visit 4 Date**' (dd/mm/yyyy) and '**Planned Visit 4 Time**' (HH:MM) into the adjacent boxes. Click '**Save and exit'**.



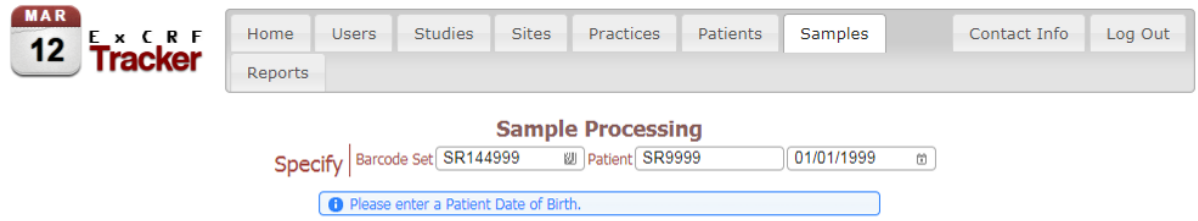
SAMPLE REGISTRATION

1. Once logged in to CRF Tracker, click on the '**Samples**' tab, then the '**Process Samples**' button.

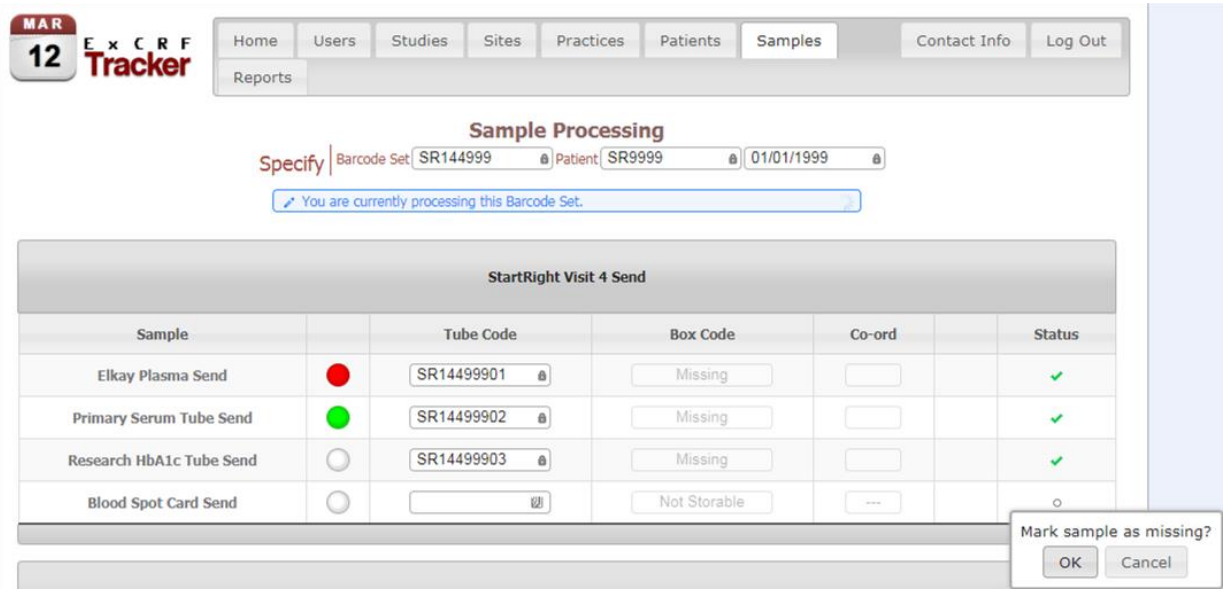


2. Scan or manually enter the 8 digit Barcode Set number which has been assigned to the participant into the first field labelled 'Barcode Set'. If entering the Barcode manually, do not include any hyphens (SR14XXXX). Press the '**return**'(↵) or '**tab**' (↹) key, and wait for the 'Patient' field to open.

   Type the participants study ID (SRXXXX) into this field and press the '**return**'(↵) or '**tab**' (↹) key. Enter the participants Date of Birth (dd/mm/yyyy) in the final field, then press the '**return**'(↵) or '**tab**' (↹) key to load the Sample Processing page.



3. Scan or manually enter the barcodes from the Plasma Elkay tube, the 8.5ml Primary Serum tube and the 3.0ml EDTA Research HbA1c tube in the “StartRight Visit 4 Send” section (if you are manually entering the number, do not include any hyphens). Once each sample has been registered, press the **return**’(↵) or ‘**tab**’ (⇆) key on your keyboard and a green tick will appear in the “Status” column as shown below.



4. If any of the above samples have not been collected then please mark the sample as missing on CRF Tracker:
   a. Click on the circle in the “Status” column that corresponds with the missing sample.
   b. Select “OK” when asked if you would like to “Mark sample as missing?”
   c. A question mark will appear in the “Status” column.

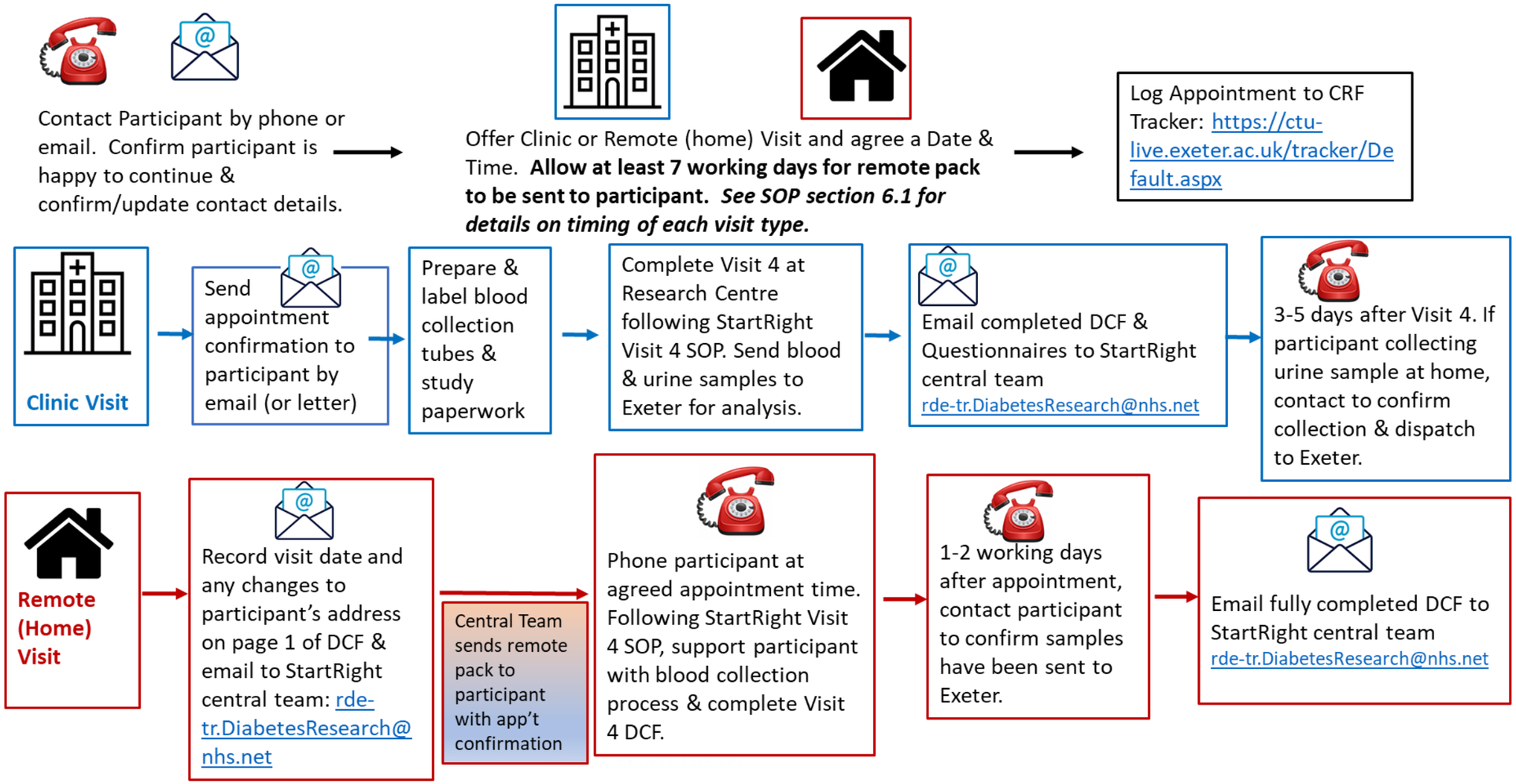
APPENDIX C: STARTRIGHT STUDY RESEARCH BLOODS PROCESSING TABLE

PLEASE FOLLOW TUBE PROCESS FROM LEFT → RIGHT

Tube Name	Primary Tube Description	Label Tube With	Processing	Scan or Enter Barcode to CRF Tracker	Form to Use	Label Form With	Package	Dispatch on Day of Collection
6.0ml K2E (EDTA) BD Vacutainer		**Label for Research Primary Plasma Tube**	Gently **invert 8-10 times** to ensure blood mixes with tube additives. Centrifuge at **1300g** for **10 minutes** (see centrifuge conditions in Appendix A). Use the pipette to transfer the plasma from the EDTA primary tube, into the Elkay tube and seal securely with the blue lid. Dispose of the EDTA primary tube and remaining contents in accordance with local protocol.					
Elkay Plasma Tube		**Label for Elkay Plasma Tube** **AND** **Patient Name & Date of Birth**		YES Elkay Plasma Send Tracker symbol: ●	Exeter Biochemistry Request Form	**NHS Number, Date of Birth, Surname, First Name, Gender** AND **Sample Date & Time** AND **StartRight Study ID** AND **Label for Exeter Biochemistry Form**	Place the 3 tubes in the absorbant pocket provided and then into the plastic sample bag with the completed and labelled 'Exeter Biochemistry Form'. Label the 'Urgent Research Samples for Chem MTO' form (A4 sheet in red type) with the **Label For Exeter Lab Instruction Form**.	Place the bag of samples and 'Urgent Research Samples for Chem MTO' form in the postage paid jiffy bag provided. **THE SAMPLES MUST BE SENT TO EXETER ON THE DAY OF COLLECTION.** **PLEASE ENSURE THAT THE SAMPLES ARE 'IN TRANSIT' ON THE DAY OF COLLECTION AND DO NOT REMAIN IN A POST BOX OR HOSPITAL ROOM OVERNIGHT.**
8.5ml SST II *Advance* BD Vacutainer		**Label for Research Primary Serum Tube** **AND** **Patient Name & Date of Birth**	Gently **invert 5-6 times**. Leave to **stand until clotted** in an upright position. Centrifuge at **1300g** for **10 minutes** (see centrifuge conditions in Appendix A).	YES Primary Serum Tube Send Tracker symbol: ●				
3.0ml K2E BD Vacuatainer		**Label for Research HbA1c Tube** **AND** **Patient Name & Date of Birth**	Gently **invert 8-10 times**.	YES Research HbA1c Send Tracker symbol: ○				

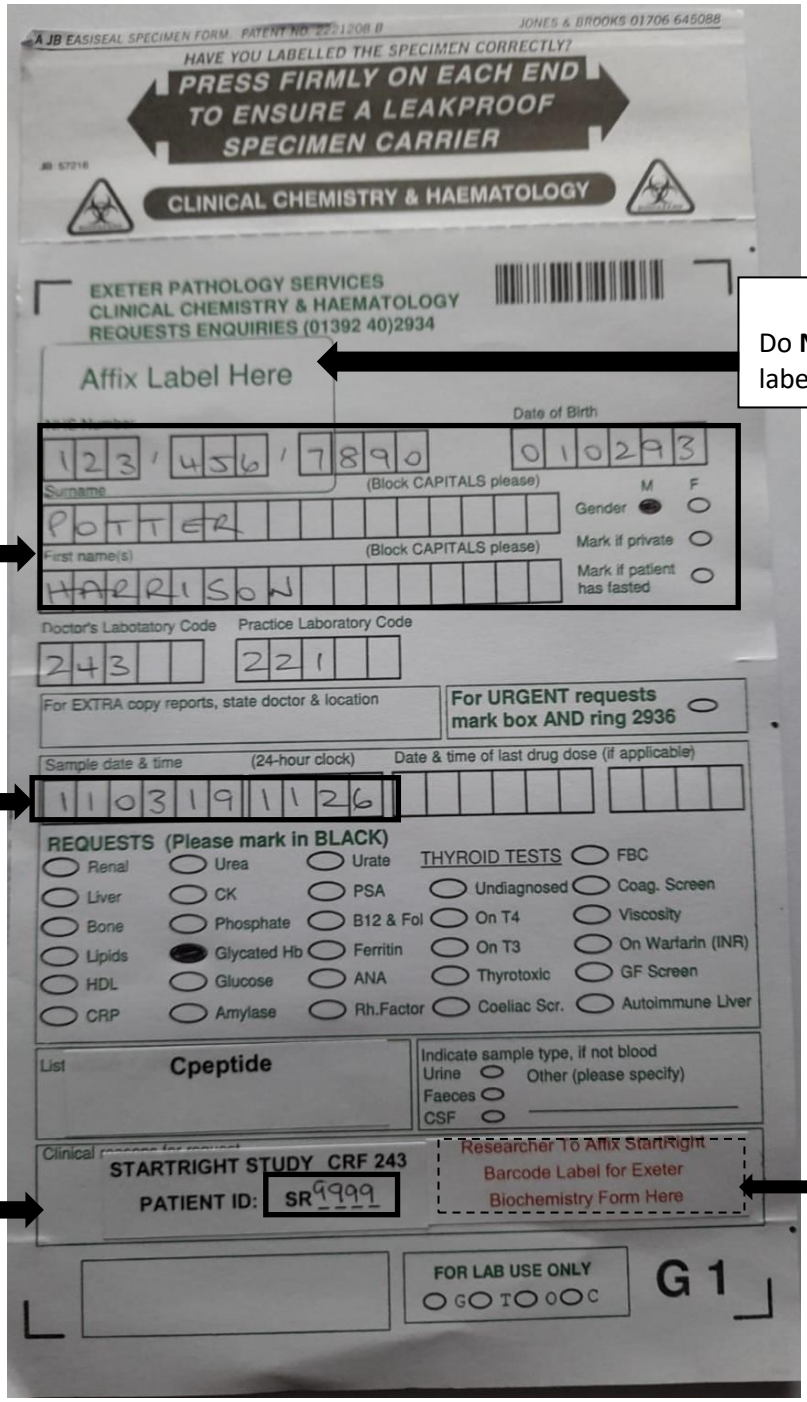
APPENDIX D

STARTRIGHT VISIT 4 SUMMARY PROCEDURES



APPENDIX E: EXAMPLES OF COMPLETED BIOCHEMISTRY FORMS FOR RESEARCH SAMPLES

COMPLETED BIOCHEMISTRY FORM FOR RESEARCH BLOOD SAMPLES



Enter the participant's: **NHS number, Date of Birth, Gender, Surname, Forename**.

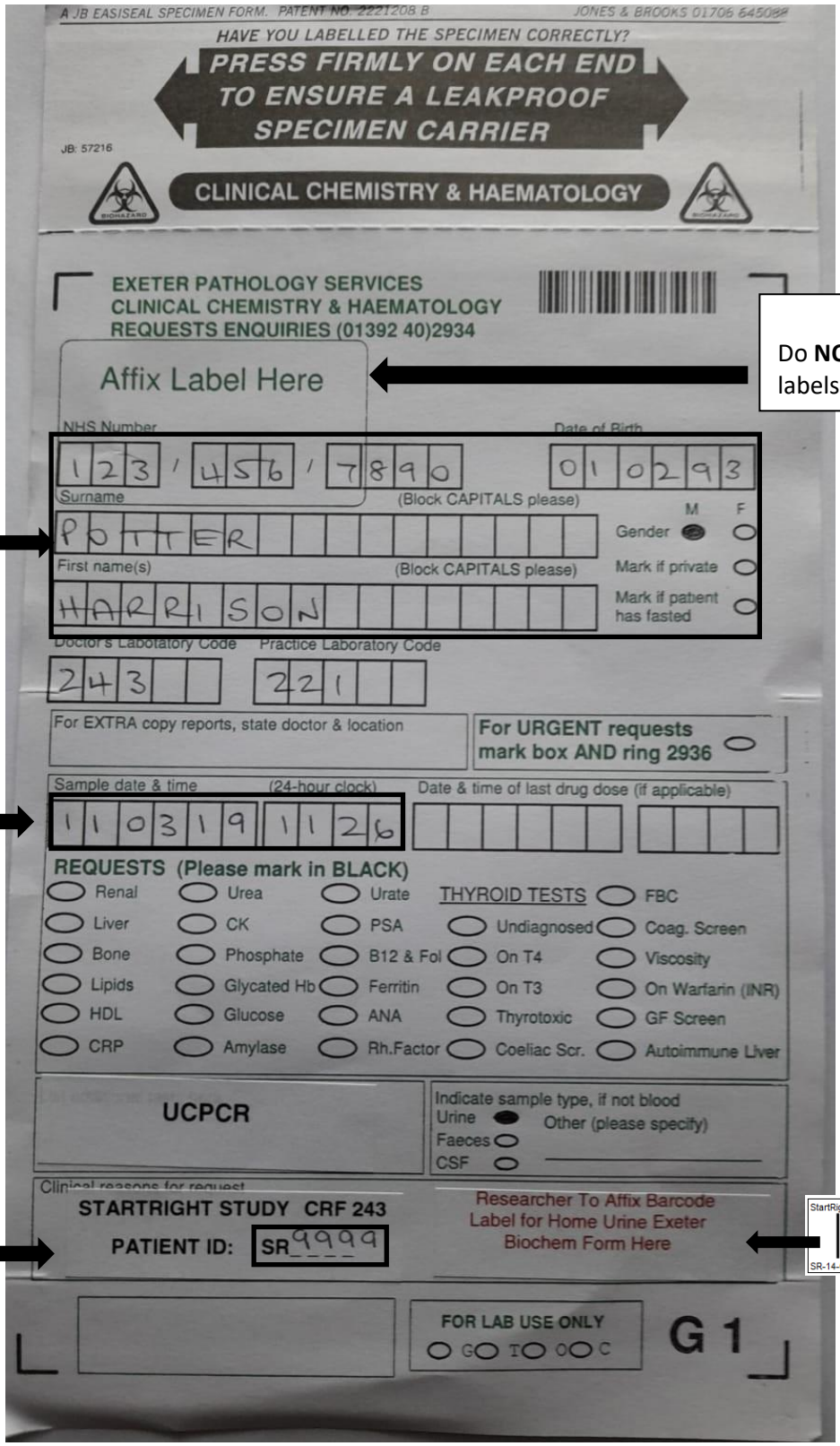
AND

The **date** and **time** samples were taken.

A**ND**

The participant's **Study ID.**

EXAMPLE OF COMPLETED BIOCHEMISTRY FORM FOR URINE SAMPLES



Do **NOT** affix any labels in this box

Enter the participant's: **NHS number, Date of Birth, Gender, Surname, Forename**.

AND

The **date** and **time** samples were taken.

AND

The participant's **Study ID.**