NatCen
Social Research that works for society

Diet and Health Study 2015

Fieldworker Project Instructions

Contents.

1 Background & Aims

Consumption of dietary sodium (or salt) is related to high blood pressure and cardiovascular disease. Salt consumption can be assessed by measuring sodium levels in urine, ideally in a sample collected over a 24-hour period.

Public Health England (an executive agency of the Department of Health) and the Food Standards Agency Northern Ireland have commissioned this study to monitor progress towards the dietary target to reduce salt intake to approximately 6g per day. This matters because too much salt has been linked to increased blood pressure – the main risk factor for Cardiovascular disease, the biggest killer in the UK and the Western world, and stroke. The study is being carried out across Northern Ireland and involves adults aged 19-64. The aim is to collect usable 24-hour urine samples from a minimum of 550 adults in Northern Ireland.

Avoid mentioning *the term* ***'salt'*** *to the participant*

We do not want people to adjust their diet for the purpose of this study

If asked about nutrients or dietary markers simply mention nutrients

'such as sodium or potassium'

Individuals will initially be recruited by NatCen's Telephone Unit (TU) via Random Digit Dialling across 45 postcode sectors. Details of those agreeing to take part will then be passed to the fieldworker stage. At this stage participants will be asked to collect all urine passed during a 24-hour period. Since the level of sodium in urine fluctuates according to what was eaten at the last meal and how much fluid an individual has drunk, and because salt is the predominant source of sodium in the UK diet, a urine collection over 24 hours is accepted as being the most reliable method for assessing salt intake in the population. You will need to conduct two short visits to each household. During the first visit, you will need to explain the procedures and leave the collection equipment. You will then collect the 24-hour urine collection on the second visit, complete the collection sheet and despatch note and send them to the laboratory for analysis.
Fieldwork is being carried out in five waves: TU are carrying out recruitment in January-June, and fieldworker appointments will be carried out during February – July.

NatCen is conducting the telephone recruitment, Ulster University is conducting the fieldwork and MRC Human Nutrition Research (HNR) will be responsible for the analysis of the urine samples.

The study has received ethical approval.

2 The Research Team

Ulster University		
Liadhan McAnena	Scientific Officer in Nutrition	02870 123398 or 07751 340 134 l.mcanena@ulster.ac.uk
Maeve Kerr	Lecturer in Food Regulatory Affairs	02870 123515 ma.kerr@ulster.ac.uk
Barbara Livingstone	Professor of Nutrition	02870 124471 mbe.livingstone@ulster.ac.uk
NatCen		
Research		
Katharine Sadler (until March 18th)	Senior Researcher	0207 549 7102 Katharine.Sadler@natcen.ac.uk
Natalie Maplethorpe (after March 18th)	Senior Researcher	0207 549 8523 Natalie.maplethorpe@natcen.ac.uk
Keeva Rooney	Researcher	0207 549 9564 Keeva.Rooney@natcen.ac.uk
Bev Bates	Research Director	0207 549 7013 Beverley.Bates@natcen.ac.uk
HNR		
Sonja Nicholson	NDNS Co-ordinator	01223 437574 Sonja.Nicholson@mrc-hnr.cam.ac.uk
Equipment - Sarah Gibbings	Equipment co-ordinator	sarah.gibbings@mrc-hnr.cam.ac.uk (preferred contact) 01223 43 6711
Kate Guberg	Senior Analyst	01223 437534 Kate.Guberg@mrc-hnr.cam.ac.uk

3 Summary of Survey Design

The fieldwork structure is as follows:

Stage 1

TU recruitment

- Select up to 2 adults
- Check eligibility
- Gain agreement
- Collect contact details

- Send out advance letter with FAQ leaflet

Stage 2

Fieldworker contact

- Call household & arrange appointment
- Send appointment letter if requested

Fieldworker visit 1

- Introduction
- 24-hour urine & PABA leaflets
- Take written consent

Fieldworker visit 2

- Check collection sheet
- Weigh samples
- Sub-sample urine
- Despatch note
- £15 gift card

Stage 3

Lab analysis

4 The Sample

4.1 Sample Design

A requirement of the study is that a representative sample of the population in Northern Ireland, aged 19 - 64 years is achieved.

The initial sample will be recruited through Random Digit Dialing (RDD). RDD is a method where a representative sample of telephone numbers is generated at random from a frame of all possible telephone numbers in a postcode sector. For this study we have selected 45 different postcode sectors (points) across Northern Ireland. We aim to recruit up to 2 eligible adults per household (see section 4.3 for eligibility criteria).

Each fieldworker assignment will vary in size depending on the number of expected agreements the TU are able to achieve in a particular postcode sector, although on average we expect to issue around 38 cases per fieldworker per wave.

The required study outcome is to have collected a minimum of 550 **usable** (i.e. not just collected) urine samples that consists of a balanced sample of men and women. We estimate that this will involve **collecting around 920 urine samples in total**. Fieldwork will be monitored closely to ensure that we achieve this.

4.2 Fieldwork Waves and Sample Sizes

Wave	Start date	End date	Area	Target no. urine collections
Wave 1	23rd Feb	31st Mar	North of Belfast	194
Wave 2	25th March	7th May	South	184
Wave 3	24th April	31st May	West	184
Wave 4	25th May	29th June	North	184
Wave 5	24th June	31st July	South of Belfast	174
ALL	23rd Feb	31st July	-	**920**

4.3 Eligibility Criteria

When making an appointment, the Telephone Unit will check that participants are of the eligible age range (19 - 64 years). Exclusion criteria are:

EXCLUSION CRITERIA
Urine samples will **not** be taken from **pregnant** or **breastfeeding** women.

Participants on medication are eligible, but will be asked to make a note of certain prescribed medications taken during the 24-hour collection on the urine collection sheet. Some medication will exclude participants from taking PABA.

Participants unable to take PABA can still take part in the study. For more information about PABA see sections 9.2 and 9.5.

Women who are menstruating will be asked to collect urine on **non-period days**.

5 Overview of Fieldworker Visits

5.1 Participant Recruitment

Participants will initially have been contacted by the Telephone Unit (TU) with the aim of introducing the study and gaining agreement for you to contact them. After this short telephone interview the advance letter detailing the purpose and background of the study with the FAQ leaflet will be sent out from NatCen, stating that you will be in touch in the next few weeks.

At the start of your assignment, you will be sent Individual Case Forms (ICFs) with the participant's serial number, name, contact details, address and any information that the TU has recorded for you. The ICFs will be a key document for you to work through at Visit 1 and Visit 2 and you'll use the form to record key information about the visits (see section 6.2 for more detail on the ICF). You will also receive personalised labels with the participant's ID, sex and date of birth (DOB).

5.2 Fieldworker Appointments

You will be making your own appointments with participants via telephone. You must make contact with them within the first two weeks following the issue of work to you. If you are having difficulty making the initial contact, it is suggested that you attempt a minimum of 6 phone calls spread across different days of the week and different times of day. If you are still unable to make contact, you should then attempt to visit the participant at their house and leave a Missed Appointment card (supplied to you by Ulster). On this card you should write the name of the respondent, your name and contact information and your reason for contact. You could also circle around the freephone number so respondents have two options for making contact. Once you have made an appointment and if the participant requests, you need to send them confirmation of the appointment using an appointment letter. Please contact Liadhan at Ulster if the participant requires an appointment letter.

At the same time, **please double check sex and DOB** of the participants on the labels to ensure they match the ICF. If any of the details are incorrect or missing, please contact karen.chamberlain@mrc-hnr.cam.ac.uk or veronica.bell@mrc-hnr.cam.ac.uk at HNR (they can also be reached via the switchboard on 01223 426356) and inform Ulster University / Liadhan so that the labels can be reprinted with the correct information and sent out to you prior to the first visit. Please note that labels take roughly 7 days to be reprinted and sent to you, so ensure enough time for this.

Remember: There can be up to 2 participants per household and where possible you should aim to visit the household at a time that is convenient for both participants.

5.3 First fieldworker visit

The purpose of the first visit is to follow the procedure below with each participant:

- Encourage the participant to take part
- Answer any questions they may have
- Check eligibility using the ICF
- Provide the participant with detailed leaflets about the 24-hour urine collection instructions and PABA
- Obtain written consent
- Hand the equipment over to the participant
- Allocate a date for the participant to carry out the 24-hour collection
- Label consent form and urine collection sheet
- Arrange a date for the second visit (either the day the collection ends or the day after 24-hour collection)
- Leave the participant with a completed appointment card, to remind them when you will be returning to pick up their 24-hour urine collection.
- Record the outcome code in section 5 (or 6 and 7 when necessary) of the ICF

We estimate this first visit will take 20-30 minutes (whether you have one or two participants). Please note it is ok to discuss the information about the visits with both participants at the same time, although you will need to make sure that informed consent is taken individually and both interviews are completed appropriately.

5.4 Second fieldworker visit

This should take place on the day the 24-hour collection finishes or the day after.

During the second visit you will:

- Check the urine collection sheet with the participant
- Weigh the 24-hour urine collection according to protocol
- Complete the 24-hour urine despatch note
- Collect a sub-sample of 2 aliquots of the 24-hour urine collection

- Dispose of the remaining urine and equipment
- Label the 24-hour urine despatch note and urine monovettes
- Prepare the aliquots for despatch.
- Complete section 8 (Visit 2, all questions) of the ICF

Participants will not receive results of their urine analysis. Each participant who provides a complete 24-hour urine collection will receive a **£15 gift card** for their participation in this study.

5.5 Typical Scenario

A typical scenario might be as follows:

First Visit: e.g. Monday

- Allocate (randomly assign) and agree a day and time for the participant to carry out the 24-hour urine collection.

Day 1 collection: e.g. Wednesday

- The 24-hour urine collection should start with the morning's second urine pass and continue through the day and night.

Day 2 collection: e.g. Thursday

- The 24-hour urine collection will end with the mornings first urine pass (i.e. it should include the first morning urine pass).

Second Visit: e.g. Thursday or Friday

- You will need to weigh the sample, check the collection sheet, complete the despatch note, attach the PABA blister pack, enclose labels AL1 (9) and AL2 (10) and prepare the samples for despatch.

6 Documents and Equipment

6.1 Workpack documents

The following documents will be provided for the study:

Advance letter

An advance letter and FAQ (see below) will be sent to all participants who have agreed to take part in the study at the Telephone Unit stage. It details the purpose and background to the study, what it involves, and also tells the participant that the fieldworker will be contacting them to make an appointment. These letters will be sent out from NatCen; however you will have a copy to show participants *(An example of the advance letter is in your briefing pack).*

FAQ leaflet

A leaflet answering some frequently asked questions will be enclosed with the advance letter. This will cover common questions participants might have before of the fieldworker visit. You will have a copy of this leaflet in your work pack to prepare you for some common questions *(An example of the FAQ leaflet is in your briefing pack).*

Fieldwork appointment letter

If the participant would like to be sent an appointment letter please contact Liadhan. You will need to date (top) and sign (bottom) the letter and write in the appointment details (i.e. the date and time of visit 1 and the participant's name) before posting to the participant.

Individual Case Form (ICF)

This is a key document to take you through what's required at the first and second visits. The ICF will contain the address and name details of the participant, including serial number and telephone number(s). There may also be some useful information about the location of the household recorded by the TU. *(An example of the ICF is in your briefing pack).* You will need to complete the ICF, label the ICF and record outcome codes for each visit. **See section 6.2 for more detail.**

24-hour urine leaflet

The 24-hour urine leaflet provides detailed information for the participant about how to collect the 24-hour urine collection. The instructions cover the protocol that you will also explain at your first visit. Please read the leaflet so you know exactly what the participant needs to do for the study. You will leave a copy of the leaflet with the participant. Make sure participants have read and understood the leaflet in order to obtain informed consent. *(An example of the 24-hour urine leaflet is in your briefing pack).*

PABA information leaflet

The PABA information leaflet gives details about the PABA tablets. Each participant should be given a copy and allowed time to read through it. Participants will be asked

to take three tablets during the 24-hour collection period. PABA levels will be measured to assess how complete the 24-hour collection is (See sections 9.2 and 9.5 for further information about PABA).

However, if the participant is allergic or thinks they may be allergic to PABA **they can still take part** in the study without taking PABA *(An example of the PABA leaflet is in your briefing pack).*

Consent form

Participants should be given the instructions for making a 24-hour urine collection and the PABA information leaflet to allow them to make an informed decision about taking part (bearing in mind that people can participate without taking PABA, but their participation is more valuable if they do take it). Each participant wishing to take part in the study **must** sign the consent form. The consent form is carbonised; the participant should retain one copy and the second copy will be returned (by you) to Ulster University along with the completed ICF, who will then send on to NatCen. Completion of consent forms are checked at NatCen after they are returned, to ensure that the written consents match the samples gained and received in the lab.

Note: samples that cannot be matched with valid consent forms need to be destroyed. Fieldworkers will be informed of any errors picked up through the checking process *(See Appendix B for an example of a completed consent form).*

24h-urine collection sheet

The 24-hour urine collection sheet needs to be completed by participants during (not after) their collection. At the return visit, you need to go through the collection sheet with the participant to spot and fill in any missing information. You also need to check for 'out-of-range' samples i.e. collected for less than 20 or more than 28 hours (See section 12.1.1 for details about handling unusable samples in the household).

As with the despatch note, the collection sheet **must be sent with the samples**. See section 9.7 for details about completing this form (See Appendix C for an example of the urine collection sheet).

Despatch note

A completed despatch note **must be sent with the samples**. Details needed are the full serial number (in the form of a label), fieldworker name and number. Also needed is the weight of the collection. The 24-hour urine collection must be weighed at least twice and recorded on the despatch note.

If a participant has used both collection containers, then record the weight of urine in each container on the despatch note.

Please complete the despatch note very carefully – any errors that cannot be rectified are likely to result in the sample being destroyed. The lab will notify NatCen of any such errors and these will be passed onto fieldworkers (See Appendix D for an example of a completed despatch note).

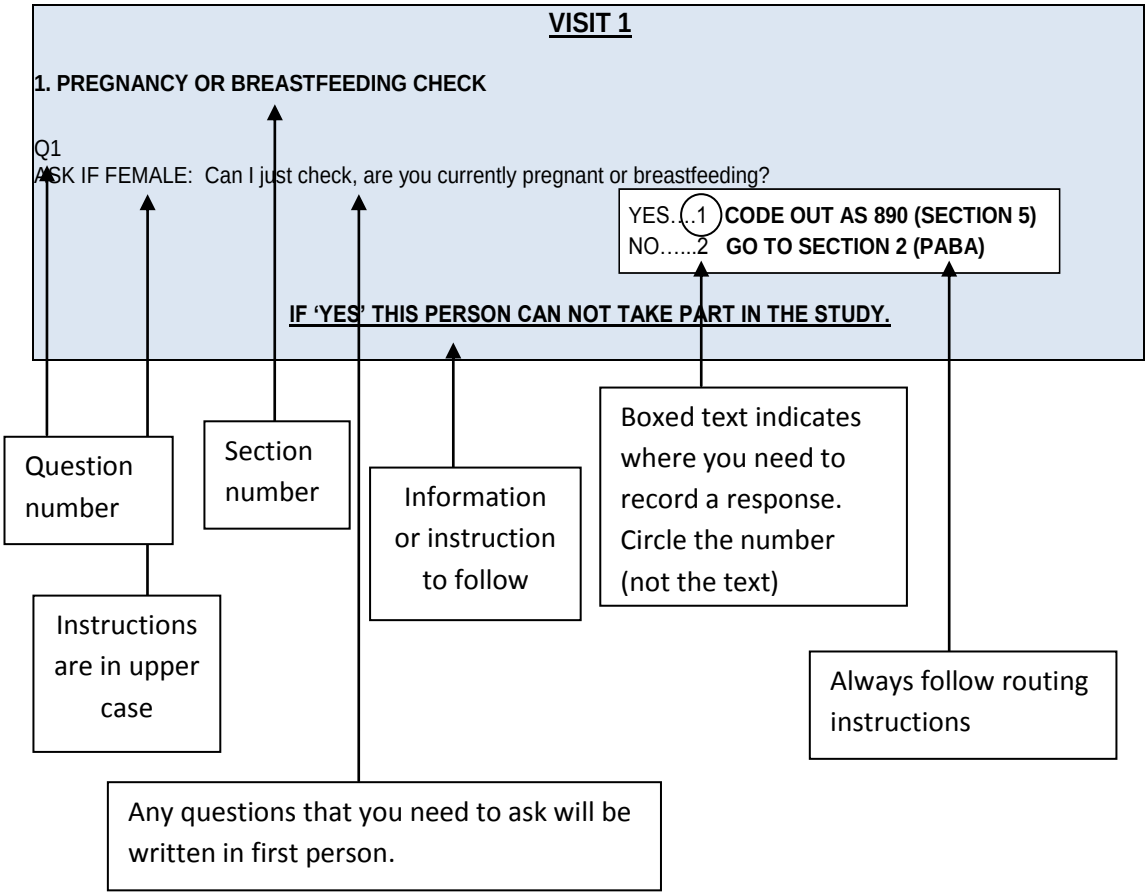
6.2 Individual Case Form - detail

This document is vital for both field visits. You will get one ICF per participant and it contains useful sample information and also guides you through the procedures you need to follow. The ICF must be completed for every participant - if the participant refuses to take part or the field visit was not made then there are outcome codes you need to record.

It is important to fill out the ICF clearly and accurately. You must therefore write clearly in block capitals (preferably in black pen). Also make sure to read the questions in the ICF very carefully and follow the instructions directly.

6.2.1 How to use the ICF

If you follow the ICF directly, you should be able to conduct productive and efficient fieldwork.



6.2.2 ICF Front Page

There is a box at the top of the page called 'Fieldworker Visit Appointments'. This is where you record the Visit 1 and Visit 2 appointments you have booked for each participant. In this box, you can record the days and dates of each visit.
Also towards the top of the page on the left hand side is the contact number of

Liadhan McAnena from Ulster University, who will be your main contact whilst conducting fieldwork.

Underneath the Fieldworker Appointments box is information about the case. This includes the name of the study, wave number (which will be populated), final outcome code of Visit 1, serial ID (i.e. that on the label) and fieldworker ID (Ulster will give you this). You must record your fieldworker ID, the final outcome code at the end of your first field visit and if the participant agrees to collect a 24-hr urine sample the serial ID number.

The final outcome code tells us if the respondent participated in the study, so you must use the outcome codes in section 5 of your ICF to record the final outcome. For example, if the participant refused at the first visit, you would code this as 830 or 840 in the final outcome box. However, if the participant completed the first visit, but did not provide a urine sample at the second visit you would code this as 810, as the first field visit was made. We will be checking section 8 to see whether a urine sample has been provided, so do not note this down in the final outcome box.

Personal Information
On the front page of the ICF is a personal information box. In this, you will find the participants unique serial number, the address and postcode of the participant, telephone numbers of the participant, the CATI interview date (i.e. the date of the TU interview), the date of birth, the TU status (if they agreed or refused contact), gender of the participant and any location details (e.g. door to use, preferable hours etc.). It also has a space to affix the serial ID label. You must match the right label to the right participant, as the information on the label will be used to identify the sample.

Sometimes you will receive an ICF with no address, DOB or sex written on it. This is usually because a participant felt uncomfortable giving their personal details over the phone to an interviewer. When you make initial contact, make sure you ask for any missing information and add this to the ICF. If the sex or DOB is missing, then make sure to immediately contact HNR to request the correct labels for that participant.

The CATI interview date can be quite useful information to use during your introduction (e.g. “I see that you were told about the study on the 01/03 by our Telephone Interviewer whereby you agreed to be contacted by a fieldworker”).

6.2.3 Visit 1 - ICF

You must record eligibility to take part in the study in the ICF. You will ask participants whether or not they are pregnant or breastfeeding, or unable to take PABA tablets (due to allergic reaction or other medication). You will also explain the 24-hour urine collection, give them the appropriate documents (PABA leaflet, urine collection sheet, consent form, urine collection leaflet) and establish the start date of the 24-hour collection. The date for the next visit (visit 2) must be made before leaving the participant.

Section 1: Pregnancy and Breastfeeding check

Q.1- Ask if the female participant is pregnant or breastfeeding. If the participant is pregnant or breastfeeding they cannot take part in the study. This is because they have specific nutritional circumstances that may skew our results.

Section 2: PABA Eligibility

You must establish whether the participant can take PABA tablets.

Q.1- The ICF lists sulphonamides, read out the question to the participant. If they state that they are taking any sulphonamide-based medication, they cannot take PABA tablets but they can still take part in the study. Sulphonamides are commonly used as antibiotics, and the taking of PABA can interfere with the antibiotic. While this is not directly harmful to the participant, PABA may stop the antibiotic from working.

Q.2- You must also check whether the participant is allergic or intolerant to hair dye, sunscreen, vitamins/ dietary supplements or lactose. If they answer 'yes' to any of these, then they cannot take PABA tablets. This is because some sunscreens and hair dyes contain PABA so if the participant is allergic, it could indicate that they are also allergic to PABA. PABA also contains a very small amount of lactose, so someone who is lactose intolerant should not take PABA. Some dietary supplements and vitamins contain components of PABA, so this could also indicate an intolerance or allergic reaction to PABA. Generally speaking a person would know if they were allergic to any of these items, so if they are unsure, assume that they are not allergic and continue to question 4.

Q.3- If the participant has answered 'yes' to the PABA eligibility questions 1 or 2, then they are not able to take the PABA tablets. They can however still provide a urine sample.

Q.4- You must tell eligible participants about PABA using information in the ICF and the PABA leaflet. While telling them about the PABA tablets, you should also go into detail about the urine collection, and hand them a leaflet if they don't already have one. Allow them to read the leaflets and ask questions. It is important that the consent they give is informed, meaning that they must understand all parts of the study, including collecting the sample and how it will be used.

Q.5- You must ask the participant if they are willing to take the PABA tablets. If they refuse, they can still take part in the study.

Q.6- Explain to the participant that you must collect all PABA packaging on your second visit, so advise them not to throw the packaging away after use. This is so we can see how many tablets they have taken over the 24-hour period, and helps HNR analyse the urine properly.

Q.7- After you have worked through questions 1-6, the ICF will then prompt you to ask the participant to initial boxes 3 and 4 on the consent form, and make sure that they also sign and date the form.

Section 3: Day of Urine Collection

You must randomly select a day to start the 24-hour urine collection. Try and make this a week day if possible with the participant. Make sure both you and the participant fully understand the day that they must start their collection on. See section 9.6 for more detail on this.

Section 4: Urine Appointment Checklist

This is a checklist that reminds you to do things before you leave the visit. It is very important that you go through all items carefully and ensure that they are all filled out correctly. Section 4 must be followed while still with the participant as it includes certain prompts that must be done by the participants (e.g. making the next appointment, going through the collection sheet to make sure they know when to take PABA).

Section 5: Outcome of Attempt to Interview Participant

Here you must use outcome codes to record the result of the first visit. This is used to establish whether a field visit was or wasn't made and the reasons for this and is information required to monitor response and used in the final report. Even if the field visit was not made or the participant refuses, you must still fill out the ICF and code as appropriate.

Section 6: Complete if Person Refused to Take Part (Codes 830/840)

Only fill out if you coded 830 (refusal by person) or 840 (proxy refusal) in section 5. Here, you must code their reason for refusal.

Section 7: Complete if Broken Appointment, Ill, Away or Other Unproductive (Codes 850-890)

Only fill out this section if the field visit was not made due to reasons other than refusal. Only complete if you coded 850-890 in section 5. In this section you must give full details on unproductive participants (who have not refused). It is important that you write clearly.

Finally, make sure you have given the participant all the equipment and documentation needed and remind them about the time and date of their collection and your second visit before thanking them for their participation and leaving the household.

6.2.4 Visit 2 - ICF

In this visit, you will weigh, mix and sub-sample the urine sample, check the urine collection sheet and prepare for despatch. It is very important that you stick to protocol for weighing the sample as our research is dependent on correct data

Section 8: Urine Collection

Q.1- This is an important question on your ICF as it tells us if the participant provided a urine sample. This is key variable in our research and so it is very important to record clearly. If a participant has not provided a sample, you will need to provide a reason for this in Q.7. Go straight to Q.7 if they have not provided a sample, as the rest of the ICF does not apply to them. The participant will not get the £15 gift card. If the participant has provided a sample, continue to fill out the rest of the ICF.

Q.2- Now you must weigh the sample. Make sure to follow the protocol exactly, as we need an accurate weight. **You then need to ensure the urine collection sheet, consent form and dispatch notes are completed accurately.** Tick off each in the boxes provide when you've completed them.

Q.3- You must note down on what day the participant started their urine collection.

Q.4- You must ask participants whether they had taken any dietary supplements during the 24-hour urine collection. This should also be noted down in the urine collection sheet, so make sure you check the collection sheet thoroughly.

Q.4a- Only fill out this question if the participant did take dietary supplements. List all the supplements that the participant mentions. It is important to note these down as dietary supplements can change the nutritional composition of their sample. Dietary supplements will be taken into consideration when analysing the sample.

Q.5- You must ask the participant if they have taken any diuretics or water tablets during the 24-hour urine collection. Diuretics increase urine excretion and can skew our results as the urine is less concentrated. It is therefore important to note this down as we can then take it into account when analysing results. If the participant is unsure, explain that diuretics are often taken to help with ankle swelling, high blood pressure and heart failure. Generally speaking, a person would know if they were taking a diuretic, so if they are still unsure, assume that they are not taking any and continue on to Q.6.

Q.5a- You will be presented with a list of diuretics. Therefore only answer this question if the participant stated that they had taken diuretics. Tick all the diuretics that apply.

Q.6- Once you have collected all the information needed from the participant and followed all necessary procedures you can thank the participant and give them the £15 gift card (see section 14 for more information on how to issue gift cards).

Q.7- Only fill out this section if at Visit 2 you return to find that the participant did not provide a urine sample. You must code reasons for why they did not provide a sample. Once you have filled this out, thank the participant for their time. Do not give them a gift card as they have not provided a sample.

6.2.5 Outcome Codes

There are a set of outcome codes for Visit 1 (see page 3 of the ICF) and some for visit 2 (see questions 1 and 7 for Visit 2 on pages 4 and 5 of the ICF).

Visit 1 codes are as follows:-

- **800- 'Refused field visit and still refuses':** Highly unlikely you'll need to use this as all cases issued to you should have 'agreed' with the telephone interviewer to you contacting them. If for some reason you get issued with a case who 'refused' at the telephone stage (may be if another person in the household agreed but they didn't) then try to encourage them to take part. If they still refuse though use this code.
- **810- 'Field visit made':** You code this if the field visit (visit 1) was made. Most people who agree to the field visit do go ahead with it and provide a urine sample. However, if the field visit was made but a sample was not given, you would still code this as '810' as the field visit was still made. Similarly, if the participant refuses after you have explained protocol or asked questions from Q.2 and onwards, you would still code this as '810' as the field visit was made even though it wasn't successful.
- **820- 'Field visit not made- No contact made':** Only use if you could not contact the participant by telephone or in person.
- **830- 'Field visit not made- Refusal by person':** This should be used if the participant refused to take part when you made the initial contact.
- **840- 'Field visit not made- Proxy refusal':** This should be used if you are at a household with two eligible participants, and one refuses on the others behalf. This is usually made clear during the initial contact.
- **850- 'Field visit not made- Broken appointment':** Use if the participant agreed to visit 1 when you first made contact and made an appointment, but then was not there when you turned up for the appointment. Try to rearrange the visit at least twice if possible. If the ultimate outcome is a broken appointment, then you must code as appropriate.
- **860- 'Field visit not made- Ill (at home)':** Use if the participant is unable to participate due to illness.
- **870- 'Field visit not made- Ill (in hospital)':** Use if the participant is unable to participate due to illness.
- **880- 'Field visit not made- Away (other reason)':** Use if the participant is away during the course of the study.
- **890- 'Field visit not made- Other'**- Use if the field visit was not made for any other reason.

All the above outcome codes are listed in section 5 of your ICF.

To record your answers, you must complete the outcome codes for each participant. This is done by simply circling around the corresponding number.

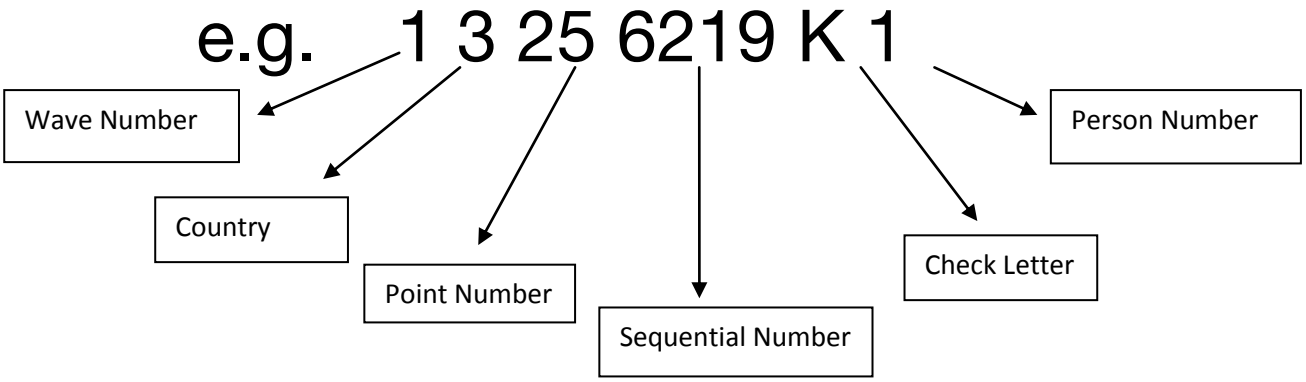
The outcome codes are always placed beside the corresponding statement, so there is no need to remember all the possible outcome codes. It is very important to code throughout the ICF when prompted. It is important to circle clearly around the number and not the statement. When the data in the ICF is analysed, it is the numerical codes themselves that are used in analysis, not the statements. Because of the scale of this study, coding makes analysing vast amounts of data a lot easier.

Please complete outcomes for each participant when prompted in your ICF. Even if the participant does not wish to take part at the field visit stage you will still need to record the final outcome code for each participant, particularly details of any refusals and reasons for unproductives.

7 Serial Numbers

Each individual in the survey has been assigned a unique identity number called the 'serial number'. The serial number can be found populated in the sample details box at the top of the Individual Case Form (ICF) – it is the field 'SER'.

This number allows us to distinguish which documents relate to which person. It is made up of different components:



Wave Number	The first digit indicates the wave (waves 1 through 5)
Country	The second digit indicates the country (3=Northern Ireland)
Point Number	A two digit number for the point
Sequential Number	A four digit number for the household.
Check Letter (CKL)	A letter of the alphabet to uniquely identify the household.
Person Number	The last digit will be a number assigned to each person in the household. This can only be 1 or 2.

8 Making Contact

8.1 Introducing the study on the phone

What to say when introducing the study and booking appointments on the telephone:

- ***Thank you for agreeing to take part in this study.***

What is the purpose of this study?

"This study has been commissioned by the Food Standards Agency Northern Ireland and Public Health England. Its aim is to monitor nutrient levels in people's diets measured in 24-hour urine samples."

What do I have to do?

- I'd like to visit you in person to go through exactly what's involved in more detail.
- You will be asked to collect all the urine you produce over a full 24-hour period to participate in the study.

How long will the study take?

- We will ask you to collect urine for a full day i.e. 24 hours. You will collect urine at home and outside the home.
- The 24-hour urine collection needs to be collected over a continuous 24-hour period and it is essential that you collect all the urine you produce over this time. I will visit again to pick up the full collection shortly after completion.

What do I get from the study?

- You will receive a £15 gift card upon completion of the study as a token of our appreciation.

Why can't I have my results?

- Your nutrient levels will vary depending on what you have eaten recently. For example, if you have had a take-away, your nutrient levels may be quite different to what they would be otherwise.
- Although results are not reliable at an individual level, they provide a good measurement of nutrient levels for groups of people.

What will happen with the results of the study?

- The information will be used to assess nutrient levels in the population and will provide vital information about diet in Northern Ireland at this time.

8.2 'Selling' the study

The Diet and Health Study is a challenging project to sell on the doorstep, but getting good participant response is crucial to achieve our target of 550 usable samples!
It is critical that participants, who agreed to be contacted by the fieldworker, can be convinced of the value and importance of the study by the fieldworker and eventually take part.
In addition to existing documents, you may find some of the suggestions below helpful when discussing the 24-hour urine sample.

Selling points on the phone / doorstep

- "24-hour urine results are very important to inform health policy making in Northern Ireland"

- "We cannot measure the same information in any other way. Bio-samples are the best tool for measuring how healthy we are."

- **If telephone interviewer impression was negative:**
  "I am sorry you were unhappy with the interviewer who called you. I apologise, but would like to reassure you that I am here to explain the study in more detail. And I will answer any questions you have before you make up your mind about taking part."

- **If reluctant after proxy-agreement:**
  "Rest assured: you have not been signed up for anything. I am here to explain the study, what's involved and why it is important, before you to decide whether you would like to take part.
  We want your urine and are happy to show our appreciation with £15 gift-card."

Common refusals and how to respond

I'm too busy for that!

- We can find a time a time and day that suits you.
- The start day of collection should still be random, but it is better to offer flexibility than to lose a sample.
- The collection tools are portable and wrapped discretely.
- No matter how busy we are, we all need to do 'our business' and we just ask you to collect it in a bottle for 1 day.

Why do you want my urine anyway?

- The Food Standards Agency Northern Ireland and Public Health England are interested in what people eat. 24-hour urine samples give evidence of the nutrition status of the general population. We need a lot of samples from different people to represent the whole country.
- PHE/ FSA NI use the results to inform and monitor food policies and recommendations.
- The results inform industry pledges to improve foods in supermarkets and restaurants to be healthier.

Why 24 hours?

- A one-off urine sample only shows what a person ate or drank recently. When looking at the nutrition status, we need all urine that is passed through the kidneys over 1 day.

I didn't know it was 24 hours, you should have told me.

- [Show advance letter and FAQ leaflet] Our telephone interviewers do not know enough about the study to explain the urine collection in detail.
- Our information letter explains that there will be a 24-hour sample collection.

9 Visit 1

9.1 Checklist of documents & equipment

Participant documents	Purpose
FAQ leaflet	*Enclosed with the advance letter*
Individual Case Form (ICF)	To guide you through the procedures and to record key outcomes on.
24-hour urine leaflet	Use to explain 24-hour urine collection when obtaining consent. Leave with participant.
PABA information leaflet	Give to participant to inform about the purpose of PABA, when introducing the 24-hour urine collection.
24-hour urine consent form	Complete with participant after 24-hour urine has been explained and questions are answered. Ensure consents are initialed. Leave one copy with the participant and deliver the other copy to Ulster.
24-hour urine collection sheet	Give to participant to complete during collection as instructed. Check when collecting their 24-hour urine collection at the second visit. Enclose with aliquots of 24-hour urine collection sent to lab.
24-hour urine despatch note	Complete on visit 2 once urine has been weighed twice. Enclose with aliquots of 24-hour urine collection sent to lab.
Equipment used by participants	**Purpose**
3 PABA tablets	To verify completeness of the 24-hour collection
5L screw cap container	Collection container for urine.

(upon request) 2L screw cap container	For collections made away from the home. Can also be used as an overflow container should the participant fill the 5L container.
1L plastic jug	For the participant to pass urine into and decant into the 5L container
Funnel	To aid decanting urine from the plastic jug into the 5L container.
Plastic carrier bag	For transporting the equipment when away from home.
Safety pin reminder	For the participant to pin the under- and outer- garments together during the period of the collection to remind that the urine about to be passed needs to be collected.
Coloured stickers	To distinguish equipment between 2 participants in the same household

9.2 PABA Eligibility

Section 2 of the ICF. If participants are eligible (i.e. they are not pregnant or breastfeeding), you need to explain the purpose of the 24-hour urine collection and the use of PABA, explain the instructions for collection in detail, obtain consent and provide participants with the information leaflets for 24-hour urine and PABA together with the equipment needed for the study.

Participants who are lactose intolerant or allergic to the following cannot take PABA but are still eligible to take part if they are willing to carry out the 24-hour urine collection:

- vitamin preparations
- hair dyes
- sunscreen lotions

Participants who take sulphonamide based antibiotics are also excluded from taking PABA. See 9.5 for list of sulphonomide based medication.

Participants on other (non-sulphonamide) medication are eligible, but you will need to ensure that the participant has made a note of prescribed medicines and dietary supplements taken during their collection period on the 24-hour urine collection sheet.

Participants are still eligible if they refuse to take PABA but are willing to carry out the 24-hour urine collection, although their participation is more valuable to us if they do take it.

9.3 Informed Consent

It is important that the participant fully understands the study. Therefore you will be required to answer any questions the participant may have. If the participant is willing

to take part, they must **initial and sign** the consent form to indicate that they have read the 24-hour urine leaflet and PABA leaflet and would like to take part in the study. It is equally important that you counter sign the consent form in the presence of the participant. The consent form must be completed by both the fieldworker and the participant in order to use the sample. Remember to label the consent form (see section 10 for more detail). See Appendix B for an example of a completed consent form.

9.4 24-hour urine collection

The 24-hour urine collection period should **start with the second void** of the morning. The 24 hour period will last throughout the night and will include the first morning void on the following day. For example, if the participant starts the 24-hour collection with the second morning void on a Tuesday then they stop collecting after their first morning void on Wednesday.

The participant must record the first void of the day on the urine collection sheet but should not collect this. This is because we are analysing all urine that has been passed through the kidneys into the bladder in 24 hours. Once the participant has passed urine for the first time of that day, they must then take the PABA tablets. All subsequent urine will then be recorded and collected, as this gives us a complete 24 hour analysis.

During the period of collection, ask participants to pass all urine in to the plastic jug and then pour it in the 5L container using the funnel provided. **It is extremely important that all urine produced over the 24-hour period is included in the collection.** During this period, ask participants to pass stools after passing urine, so that urine is not lost. If some urine is lost, please advise the participant to note the missed collection on the urine collection sheet. If a participant expects to be away from home during the collection period, they can request a smaller 2L collection container and take this with the jug and funnel with them instead of the larger 5L container. However, on return anything collected into the 2L container should be transferred to the main 5L collection container.

Advise women not to collect urine on period days.

24 Hour Urine Collection Instructions

Choose a **START** time suitable for both days (e.g. 7AM)

At **START** time Day 1, go to the toilet as normal and DO NOT collect urine. Note time on urine collection sheet

AT START time Day 1, take PABA tablet 1 and note time on urine collection sheet

Pass all subsequent urine into the jug and add to the 5L container. Keep container in a cool place and note any missed collections in urine collection sheet

4-6 hours after taking tablet 1, take PABA tablet 2 and note time on urine collection sheet

Pass all subsequent urine into the jug and add to the 5L container. Keep container in a cool place and note any missed collections in urine collection sheet

4-6 hours after taking tablet 2, take PABA tablet 3 and note time on urine collection sheet. Keep PABA packaging to give to fieldworker

Pass all subsequent urine into the jug and add to the 5L container. Keep container in a cool place and note any missed collections in urine collection sheet

Exactly **24 hours after** START time (e.g. 7AM) pass urine into the jug and add to the 5L container. The urine collection is now **FINISHED**. Write time on urine collection sheet

9.5 Taking PABA

Each participant will have three PABA tablets which are to be taken, as indicated on the urine collection sheet, during their 24-hour collection. The first PABA tablet should be taken at the start of the collection i.e. **after** the participant has flushed away the first urine of the day and recorded the time as the start time. The second PABA tablet should be taken 4-6hours after the first tablet and the third PABA tablet should be taken 4-6hours after the second tablet.

PABA is an intermediate in the synthesis of folic acid in bacteria. PABA is consumed in small amounts as part of our usual diet and is found in small quantities, for example, in liver, kidney, brewer's yeast, molasses, whole grains,

mushrooms and spinach, and can be made by intestinal (gut) bacteria. Larger amounts of PABA are found in some vitamin preparations. Following ingestion, PABA is passively absorbed mainly from the small intestine. From there, it enters the portal circulation. Some metabolism of PABA occurs in the liver and PABA and its metabolites are mainly excreted in the urine 6-8 hours later. This is why the results of participants who take PABA tablets are more valuable to us than those who don't. Although the urine collection sheet goes some way towards helping us analyse 24-hour collections, by measuring the amount of PABA in participant's urine, it allows us to accurately determine whether a complete collection has been made.

PABA may interfere with sulphonamide based antibiotics. Although not directly harmful to the participant PABA may stop the antibiotic from working. Please note we will not ask participants to stop any of their sulphonamide medication but simply ask them not to take PABA.

On the ICF (and below) there is a short list of sulphonamide medication that excludes participants from taking PABA.

The PABA tablet is very small and best swallowed whole. It will not dissolve in water or any other drink. If crushed between teeth PABA tastes a bit acidic and is unpleasant but there is no long lasting after taste. If the participant chooses to crush the PABA tablet, please advise them to ensure the **entire** tablet is consumed.

Analysis of the PABA will allow us to check whether the urine collection is complete, however, it is important that participants also record any missing samples on the urine collection sheet.

Sulphonamides	
Co-Trimoxazole	Sulfamethoxazole
Septrin	Monotrim
Sulfadiazine	Sultrin
Trimethoprim	

9.6 Randomly allocate start day of collection

It is important that urine samples are collected on all days of the week as our diet differs between weekdays and weekends. It is therefore important that you randomly allocate a day to the participant on which they should start the urine collection. Many participants are likely to want to collect their urine at the weekend so please encourage participants who are able to collect their urine on a week day. We encourage you to discuss the allocation of the collection day with the participant and emphasise the importance of the representativeness of the study across the whole week.

If the allocated day is:

- Wholly inconvenient for the participant
- A female participant's period day

- You're unable to return within 48 hours after collection START

THEN: Rearrange to next possible day after collection and don't rearrange to weekends on default.

If there are 2 participants in the household try to agree a date that is suitable for both participants.

9.7 24-hour urine collection sheet

You will fill in Section A, the participant details and the agreed start date for 24-hour collection. Remind the participant about when to take the PABA tablets (as indicated on the 24-hour urine collection sheet). The participant needs to complete Section B on the collection sheet during the collection period. Details needed are:

- Start date and time of 24-hour urine collection
- Date and time PABA tablets taken
- End date and time of 24-hour urine collection
- Date and time of any missed collections
- Names of medication and supplements taken during this period

We are particularly interested in participants recording the names of diuretics (water tablets) they are taking during the 24-hour urine collection period. Diuretics increase urine excretion and can skew our results as the urine is less concentrated. Most common conditions associated with taking diuretics are ankle swelling, blood pressure and heart failure.

Whilst it is important for the analysis to know about participants taking diuretics this will not influence their eligibility for taking PABA.

Common diuretics	
Frusemide/Furosemide	Metolazone
Bendroflumethiazide	Chlortalidone
Indapamide	Cyclopenthiazide
Amiloride Hydrochloride	Eplerenone
Spironolactone	Triamterene
Osmotic diuretics	Xipamide
Potassium-sparing Diuretics	Bumetanide
Diuretics with potassium	Torasemide

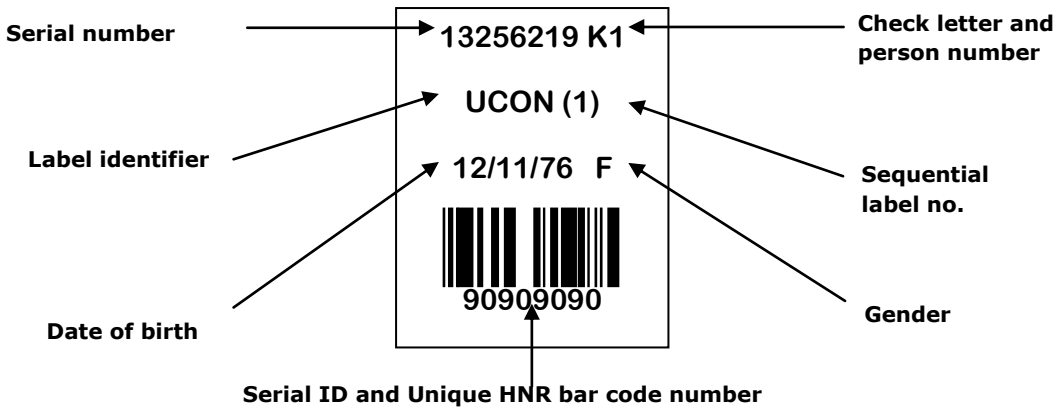
10 Labelling

You will be provided with pre-printed serial ID labels in your work pack for all cases in your point. Each set of labels will be personalized with the serial number, sex and DOB of the participant. Please ensure you are using the correct set of labels by checking that the **sex** and **DOB** printed on the label with the participant. [As stated in Section 5.2, if the sex and DOBs on the labels don't match the ICF, are wrong or are missing please contact karen.chamberlain@mrc-hnr.cam.ac.uk or veronica.bell@mrc-hnr.cam.ac.uk at HNR (they can also be reached via the switchboard on 01223 426356) and inform Ulster University / Liadhan so that the labels can be reprinted with the correct information and sent out to you prior to the first visit.]

For each participant a set of the following 10 labels will be provided rolled up as a continuous strip. You will need to use 9 of these on various documents and equipment (see detail later in this chapter).

Label	*Function*
UCON (1)	Consent form (office copy)
UCON (2)	Consent form (participant copy)
UCOL (3)	Urine collection sheet
UDESP (4)	Urine despatch note
ICF (5)	Individual Case Form (ICF)
BLANK (6)	*No function at present, blank*
U1 (7)	Urine monovette 1
U2 (8)	Urine monovette 2
AL1 (9)	For use at HNR – enclose in postal pack
AL2 (10)	For use at HNR – enclose in postal pack

Example label:



Label strips for participants that do not consent to urine should be returned to the Ulster Office as soon as their non-participation has been confirmed. This minimizes the risk of mixing up labels for new participants.

It is very important that the correct label set is used for each participant. If incorrect labels are used there is a risk of matching the 24-hour urine samples/analysis and/or documents to the wrong participant which is likely to result in the sample being destroyed.

11 Urine Appointment Checklist

REFER TO SECTION 4 OF THE ICF

REMEMBER TO DO THE FOLLOWING

1) Assign a set of labels (and so a serial ID) to the participant and affix correct labels to the front page of this form (see box 1) and both copies of the consent form and urine collection sheet
2) Initial all relevant boxes on the consent form, sign and date the form
3) Make an appointment with the participant to collect their sample, ideally on either the day they stop collecting urine or the following day
4) Explain the collection protocol
5) If the participant is taking PABA, remind them that you will be collection the packaging at your return visit
6) Complete **section A** of the 24 hour urine collection sheet
7) Give the participant the urine collection sheet and ask them to complete **section B** during the collection period.
8) Complete section 5 of the Individual Case Form (ICF)

12 Visit 2

During the second visit you will need to weigh the 24-hour urine collection according to protocol (*see section 12.2 and Appendix A*) and obtain **two** aliquots of well mixed urine. This second visit should take place on the day or the day after the 24-hour collection is completed so that samples reach HNR for further processing without further delay.

For example, if the participant collects the 24-hour urine collection between Monday morning and Tuesday morning the second visit should take place on Tuesday or Wednesday.

If the sample despatch is delayed, due to unforeseen problems, you should still send the samples as soon as possible but clearly indicate the delay in returning the samples on the despatch note.

24-hour urine collection equipment

Equipment and documents	Purpose
Salter Electron Scales	For weighing the urine collection container, always set on KG
2 x 10ml Sarstedt urine monovettes and 2 x extension tubes for urine monovettes	For aliquoting urine from the 24-hour urine collection
Labels	Two labels for Sarstedt urine monovettes U1(7) U2 (8) Participant documents (including ICF) - labels 1-5 Two labels for use at HNR, AL1 (9) and AL2 (10), to be sent to the lab with the monovettes in the postal pack
Disposable gloves Apron Work mat	Needed for handling and aliquoting the 24-hour urine collection in the household
Pre-labelled and pre-paid jiffy bag and packing material (postal pack)	For despatch of aliquoted samples
24-hour urine collection sheet	Check collection sheet completed by participant and enclose with samples
24-hour urine despatch note	Complete and enclose with samples
Coloured stickers	To distinguish equipment between 2 participants in the same household

12.1 Checking the urine collection sheet

The completeness of the 24-hour collection will be verified in two ways: through participants self-report and the use of PABA as an objective measure. During the 24-hour collection, participants are asked to record any missed collections on the urine collection sheet. Therefore, it is important that at the second visit, you check this sheet and ask participants whether the 24-hour urine collection is complete, and if not, note on how many occasions urine was not included in the collection.

If the participant has collected their urine for less than 20 hours or more than 28 hours the lab will definitely not be able to include the collection in their analysis.

Participants will **still receive the £15 gift card,** but further weighing and sub-sampling of the collection will not be necessary. You may discretely dispose of the participant's urine collection in the household's toilet.

12.1.1 24-hour urine collections out of range

Where participants have collected all their urine and completed the study over a 24 hour period, but their urine collection exceeded the duration of 28 hours or ended after less than 20 hours their collection will not be analysed.

Participants might not be fully aware of their error and will not provide you with the information straight away, which is why you need to check their collection sheet thoroughly, prompting for missing information.

As mentioned above, participants who provide a sample out of range will still receive their **£15 gift card**;

However:

- **Never** mention to participants that 'it doesn't matter for how long you collect, you will still get the £15 gift card'!
- **If in doubt** whether a sample falls within range, do despatch the samples as you would normally
- If a participant has **obviously/admittedly stopped** their collection prematurely, i.e. they have acknowledged that they have not completed the protocol; no gift card will be handed out to the participant as their participation is not productive.

12.2 Weighing the urine sample

It is important that the urine is weighed strictly according to the weighing protocol to ensure valid measurements of the collection and to allow us to do the necessary calculations. If the weight recorded is incorrect the study will not produce valid results.

We have developed a protocol that will ensure valid and accurate measurement across samples by making sure all fieldworkers follow the same procedures.

Fieldworkers working on the Diet and Health study will be accredited for following the weighing protocol using the **Salter Electro Sampson scales**. Only fieldworkers passing the accreditation will be eligible to work on the study in order that we retain the integrity and quality of the urine analysis results.

Protocol for weighing urine

The following steps should be followed when weighing urine using the Salter Electro Sampson scales. These same steps must be followed by all fieldworkers to ensure that every fieldworker is weighing urine in exactly the same way every time.

1. Ensure that the lid of the 5L container is securely fastened.
2. Before you start, check that the scales are starred to zero.

3. Place the 5L container on the middle of the hook of the scale.

4. Stand and hold the scale handles in both hands with your palms facing down. Extend your arms slightly, making sure the handles of the scale are at the level of your chest.
   Bend your elbows and hold the scale and urine approximately 18 inches (1.5 feet) from your chest, making sure you are able to hold the container still. It is critical that the container remain completely still.

5. Hold the scale and container still in position for a minimum of five seconds.

7. Record the weight and repeat the process.

The same steps should be followed if there is urine in the 2L container which cannot be transferred into the 5L container.

12.3 24-hour urine Sub-sampling Procedure

- Lay out the disposable work mat to prepare the sub-sampling
- Start by checking if there is any urine in the 2L container
- Transfer the urine in the 2L container into the 5L container if possible. If you think that only SOME of the urine will fit inside the 5L container then DO NOT TRANSFER
- Weigh the container(s) with the 24-hour collection at least twice.
- Record weight on the despatch note
- Gently invert and rotate the 5L collection container at least 20 times so that the 24-hour urine collection is mixed thoroughly, but without becoming frothy.
- Transfer some urine from the well-mixed 24-hour collection to the jug
- Collect 2 sub-samples from the 24-hour urine collection. To do so, place an extension tube onto the Sarstedt urine monovette and then draw up the sample of urine from the jug.
- Once filled removed the extension tube from the urine monovette, replace the cap and snap off the urine monovette plunger.
- Label each urine monovette using the labels U1 (7) and U2 (8) provided.

See Appendix A for an illustration of the protocol for urine monovette use.

After collecting the samples, carefully dispose of the remainder of the 24-hour urine collection in the participant's toilet (not from a height). Participants should be advised that the containers, jug and funnel can be rinsed and disposed of with the household waste or recycled.

12.4 Labelling the 24-hour urine monovettes

You will need to label and package the urine monovettes before leaving the household.

Holding the urine monovette horizontally, the correct label for each urine monovette should be peeled off the label strip. The top of the label should be positioned onto the urine monovette and then wrapped round, ensuring the label does not crease. See section 10 about what labels you should use.

13 Packaging and Despatch

Packaging will take place during the second fieldworker visit and despatch as soon as possible after the visit.

The packaging consists of the following:

- Two Noax tubes with absorbent liners (rigid tube with green lid)
- Rigid outer packaging e.g. a plastic or cardboard box
- A pre-labelled and pre-paid padded envelope

Please ensure that all samples are properly sealed. Place each urine monovette into a Noax tube. To prevent the urine monovette from getting stuck in the Noax tube, place it upright i.e. the urine monovette lid and the Noax tube lid should be together in the same orientation. Place the Noax tubes into the rigid outer packaging provided and then place in the pre-labelled and pre-paid padded envelope. Remaining labels AL1 (9) and AL2 (10) need to be enclosed in the rigid outer packaging.

The despatch note should be completed; the correct label UDESP (4) stuck on (see Appendix D for an example of a completed despatch note) and placed inside the padded envelope. Check the details on the despatch note and ensure that they are correct. Please note there is one despatch note per participant.

Samples should be despatched either the day the 24-hour collection ends or the day after.

***NB** please check the post box has a collection on the same / next day (if Monday to Friday) before you post the sample to avoid any delay in samples getting to the lab.*

Urine should only be sub-sampled and despatched if the participant has provided a complete 24-hour urine collection or a collection between **20- 28 hours**. If the participant has not completed the study (see 12.1.1 for definition), you should not sub-sample or despatch the samples.

The despatch note, participant urine collection sheet, labels AL1 (9) and AL2 (10) and the PABA tablet blister pack need to be sent with the samples to HNR using the packaging provided.

14 Gift Cards

All participants who provide a 24-hour urine collection will receive a **£15 gift card** as a 'thank-you'. Remember this should **not** be presented as 'payment' but as a token of appreciation.

You will receive a float of gift cards. They are not of any monetary value until activated by Love2shop upon receipt of your transmission.

Once a participant has provided a sample, you must contact the Incentives team at NatCen via email incentivesnisodiumstudy@natcen.ac.uk, or if for whatever reason it needs to be done urgently then phone the Incentives Team via NatCen's main switchboard on 01277 200 600. A member of the team will then active the card remotely.

When you send your email you must inform the incentives team of your fieldworker ID, the last 8 digits of the gift cards and the amount needed (£15) to activate the card, so make sure that you take note of all the relevant information. Make sure to include the project number (P10041.08) and the reason for emailing in the subject header of the email.

You must contact NatCen after every successful final visit, preferably on the same day. Contact made after 3PM on a Friday or any time within the weekend will not be addressed until the following Monday, so make sure that you inform participants of any delays. The team cannot be contacted outside of working hours (9AM-5PM; Mon-Fri). If contact is made outside of office hours, you query will not be addressed until

the next working day. Without contacting NatCen the cards will have no monetary value, so you should aim to contact NatCen soon after the final visit.

Fieldworkers should allow 24-72 hours for gift cards to activate after contacting NatCen.

If you anticipate needing more gift cards, contact Liadhan at Ulster University who will liaise with NatCen and arrange for you to be sent some more. Do this as soon as you have done your selections so that the cards will reach you before your final visit to the address.

You should write the relevant amount in the area on the top right hand side of the card, give to your participant and inform them when the card should be activated and ready (using the information above). Participants should be encouraged to check their balance before using the gift card online: https://www.flexecash.com/flexecash/love2shop-retail/balance.htm?execution=e1s1. The gift cards can only be used within the UK. The link below gives details of retailers that accept the cards and some in NI that don't: http://www.flexecash.com/flexecash/love2shop-retail/retailers.htm

There is no need to get the participant to sign a receipt.

Most participants who start the study will complete it and provide complete collections. Occasionally, participants may decide not to continue. In order to receive the gift card participants must **fully complete** the study (i.e. provide a **complete 24-hour urine collection).** Where participants attempted a 24-hour urine collection that is out of range (i.e. provided less than 20 hours or more than 28 hours) without 'giving up' they should still receive a £15 gift card for their effort.

If the participant 'gave up' during the collection period, they are not eligible for the gift card. **This should be made clear to participants during the first visit.**

14.1 Participant Feedback

We will not be sending the results of individual urine tests to participants or their GPs. If asked, use the information below to explain to participants why this is the case.

The level of nutrients in an individual's urine is heavily influenced by their dietary intake during that day.

If we were able to measure an individual's nutrient levels over a three or four day period and take an average from all the measurements, we would obtain an accurate estimate of their nutrient levels.

However, if for example an individual has had a greasy take away on the day we take our sample, their nutrient levels will be different to usual on that occasion and the individual measurement will not be an accurate reflection of the individual's regular nutrient levels.

15 Response monitoring and return of ICFs and Consent Forms

You need to record certain fields that are on the completed ICFs in the Excel Spreadsheet allocated to you by Ulster University and then hand in completed ICFs and consent forms to Ulster University on a regular basis (ideally every day or every few days). Do not post these documents. It is important you return the hard copies on a regular basis as these will be scanned and sent to NatCen every 2 weeks for keying and reconciliation.

15.1 Excel Spreadsheet Recording/Monitoring

After both field visits have been completed you must fill in the Excel spreadsheet allocated to you by Ulster University. In this, you must fill out all relevant fields for each participant. This information will then be put on to a wider database by Ulster and the information analysed for both our own internal and Client response reports. Please therefore make sure that this information is completed accurately as we will be using this to monitor the study's progress.

You will need to record personal information such as your fieldworker ID, serial number of the participant and the participant's sex. You must also record the date and outcomes of Visits 1 and 2, whether the participant took PABA, if the participant provided a sample and the day the 24-hour urine collection started. All this information needs to be taken from the relevant places in the completed ICF. You will also need to record your mileage used for that particular case. You must then upload your Excel spreadsheet in to the fieldwork file on Dropbox. Ulster University will then compile this information into their wider database. Please update the spreadsheet daily, as frequent monitoring may help us detect any possible problems or obstacles early on, which we will then be able to tackle.

You must then return the completed ICFs and Consent Forms to the Biomedical Sciences Research Institute at Ulster University on a regular basis, ideally every day or every few days. The address is printed at the back of the ICF.

Once you get to Ulster University, you can either return it via the university internal mail, or you can physically hand it in to Liadhan McAnena. To hand it in you must go to the Centre of Molecular Biosciences (CMB) and go to room W2034 which is on the second floor. If you cannot find Liadhan, alternatively you can give it to Prof. Barbara Livingstone in room W2016 (also on the second floor). If you have any issues or enquiries, you can contact Liadhan using the phone number on the front of the ICF.

16 Top Tips from Nurses

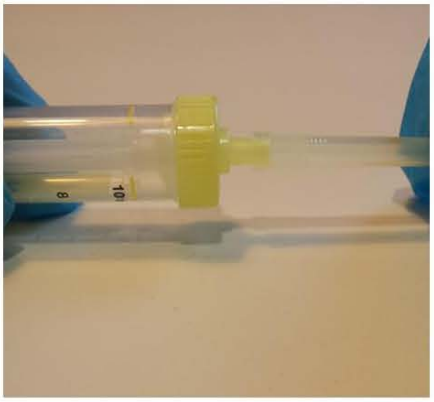
We are aware that being a fieldworker can be a bit daunting, particularly if you have not done this kind of work before. This is why we have compiled a list of tried and tested tips for having a successful interview. These tips have been compiled by our experienced nurses who worked on the England and Scotland Sodium studies and produced a very high usability rate. These practical tips are easy to follow and show that if protocols are clearly explained, participants are more likely to provide a useable sample.

1. **Have a good phone manner.** When phoning to make appointments, introduce yourself and the study straightaway. This stops them putting the phone down. Refer also to the letter they will have received. Introducing the letter reminds the participant about the study and puts them at ease which can often lead into a conversation. This builds a rapport and discourages the participant to put the phone down or refuse participation outright.
2. **Always sound and act positive.** When contacting a participant over the phone, smile and speak in a friendly manner, making sure to use positive words and phrases. This puts the participant at ease. Talk to all participants in a way that gives the impression that they want to help the project, as this can often persuade an unsure participant to participate.
3. **The procedure needs to be explained at least 3 times**, even if participant appears to understand the first time. Do not assume that just because they have read the leaflets and documents that they have understood.
    a) *First time- When they have read the leaflets*: Run through what you would like them to do. If participants appears to be wavering or uncertain at this point, make comments like "After all, it is only 24 hours out of your whole lifetime that we are asking for" in a jokey way with a smile. Participants usually laugh and agree.
    b) *Second time- When explaining PABA and the urine collection:* Explain how to take PABA and the importance of timing it correctly. Participants sometimes misunderstand the start and end times of the 24-hour collection, so explain using the collection sheet and the date that the participant has agreed to. Participants can get confused about why they record the date and time of the first passing of urine but don't save it. Equally they may be confused as to why they save the morning urine on day two. You will need to be able to explain this so make sure you fully understand why this is done. For more information about the 24-hour urine collection, see section 9.5
    c) *Third time- When they have signed up to collecting specimen:* Use the equipment (e.g.5L container, jug, funnel etc.) to explain how the specimen is collected. Focus on how easy and simple the equipment is to use.
4. **Give clear instructions about PABA during the first visit and explain at least twice why PABA is taken.** Explain the taking of PABA and the importance of timing.

5. **Explain about missed specimens.** Don't put too much emphasis on missed specimens, as this may give participants 'permission' to miss or forget a sample. Therefore you should only explain this once, and follow this explanation up with comments like "But I'm sure you won't forget" with a friendly smile. However, do make sure they understand how to record ALL specimens (even ones that have not been collected).
6. **Allow time for participant to ask questions at any stage**. Listen carefully to what participants ask. You will need to be able to pick up any misunderstandings and be able to correct them.
7. **Give them practical advice.** For example, when the participant is going to bed at night, suggest things like putting the 5 litre container on top of the closed toilet seat so that if they get up in the night, they are reminded to save their urine rather forget due to tiredness.
8. **Make sure participants understand how to store the specimen and equipment**. The specimen should be kept in a cool dark place, like a cupboard or utility room. Make sure they do not wash jug out with disinfectants after each use as this can damage the specimen. Tell them that the equipment can be washed as normal and disposed or recycled with the household waste after the collection is complete.

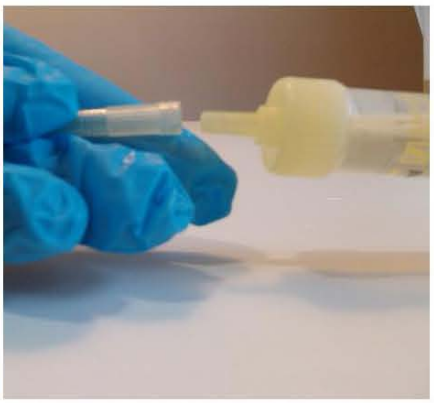
Appendix A. Sub-sampling 24-hour urine

1. Remove the small push cap.



2. Push the extension tube on the urine monovette nozzle.

3. To fill the urine monovette, pull back the plunger until you hear the click .



4. Remove the extension tube.

5. Replace the cap.

6. Break off the stalk of the plunger

Appendix B. Completed consent form

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Ulster University

Diet and Health Study 2015
- CONSENT FORM -

13 25 6219 K1
UCON (1)
12/11/76 F
9990008

MREC Reference Number: 13/EE/0417

Please use capital letters and write in ink

Please initial boxes

1. I confirm that I have read and understand the 24-hour urine leaflet dated 17.11.2014 (version 2) and PABA leaflet dated 17.11.2014 (version 2) for the above study. I have been given the opportunity to ask questions and have had these answered satisfactorily. — AD
2. I understand that my participation is voluntary and that I am free to withdraw from the study, at any time, without giving a reason and without my medical care or legal rights being affected. — AD
3. I agree to take PABA tablets to support the 24-hour urine collection. — AD
4. I consent to provide a 24-hour urine sample for laboratory analysis. — AD
5. I give permission for any remaining urine to be stored and, with ethical approval as appropriate, used in future research studies. — AD

Alice D'Arcy	**01/05/2015**	*Alice D'Arcy*
Name of Participant (Please print)	*Date*	*Signature*
Jenny Bloggs	01/05/2015	*Jenny Bloggs*
Name of Fieldworker (Please print)	*Date*	*Signature*

When completed: please retain top copy for NatCen and give bottom copy to participant

You can cancel this permission at any time in the future by writing to us at the following address:
NatCen Social Research, 35 Northampton Square, London EC1V 0AX.
Telephone: 0800 652 4572

Annex 9 24-hour urine consent v2 171114 DHS2015. For use from 01.01.2015

Appendix C. Completed 24-hour urine collection sheet

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MRC Human Nutrition Research

Ulster University

Diet and Health Study 2015

24-hour urine collection sheet

SECTION A: FIELDWORKER TO COMPLETE

13 25 6219 K1
UCOL (3)
12/11/76 F
9990006

Fieldworker Name Jenny Bloggs

Fieldworker Number 0 1

Participant Sex [ ] M [✓] F

Participant DOB 1 2 / 1 1 / 7 6

Start date of 24-hour collection 0 5 / 0 5 / 1 5

Participant consented to take PABA tablets? Yes [✓] No [ ]

SECTION B: PARTICIPANT TO COMPLETE

1. DATE / TIME OF 24-HOUR COLLECTION PERIOD

Order of events	PABA tablet taken?	Date	Time	Please tick AM	Please tick PM
START: Flush this urine away and record **start** time		05 / 05 / 15	07 : 35	✓	
1st PABA tablet **Take at start time**	Y	05 / 05 / 15	07 : 35	✓	
2nd PABA tablet **Take 4-6hrs after 1st tablet**	Y	05 / 05 / 15	12 : 15		✓
3rd PABA tablet **Take 4-6hrs after 2nd tablet**	Y	05 / 05 / 15	17 : 00		✓
END: Collect this urine and record **end** time		06 / 05 / 15	07 : 45	✓	

Note: For collections at 12 o'clock mid-day, tick PM; at 12 o'clock mid-night, tick AM.

2. MISSED URINE

It is **very** important that you collect **all** the urine you produce in the 24 hour period.

Annex 10 Urine collection sheet_NI_v2_171114_DHS2015. For use from 01.01.2015

However, if you have MISSED any urine collections, even just through spillage or overflowing, please make a note in the table below:

	Date	Time	Please tick AM	PM	Comments (e.g. spillage, overflow, full sample)
1	05 / 05 / 15	08 : 40	✓		Small spillage
2	05 / 05 / 15	23 : 35		✓	Full sample
3	/ /	:			
4	/ /	:			

3. MEDICINES AND DIETARY SUPPLEMENTS

We also need to know about certain medicines and dietary supplements/vitamins you have taken over the 24-hour urine collection.

Did you take any sulphonamide based antibiotics? Yes ☐ No ☑

Did you take any diuretics (also known as water tablets)? Yes ☑ No ☐

Did you take any dietary supplements/vitamins? Yes ☑ No ☐

If you answered YES to any of these questions, please enter the names of these in the table below:

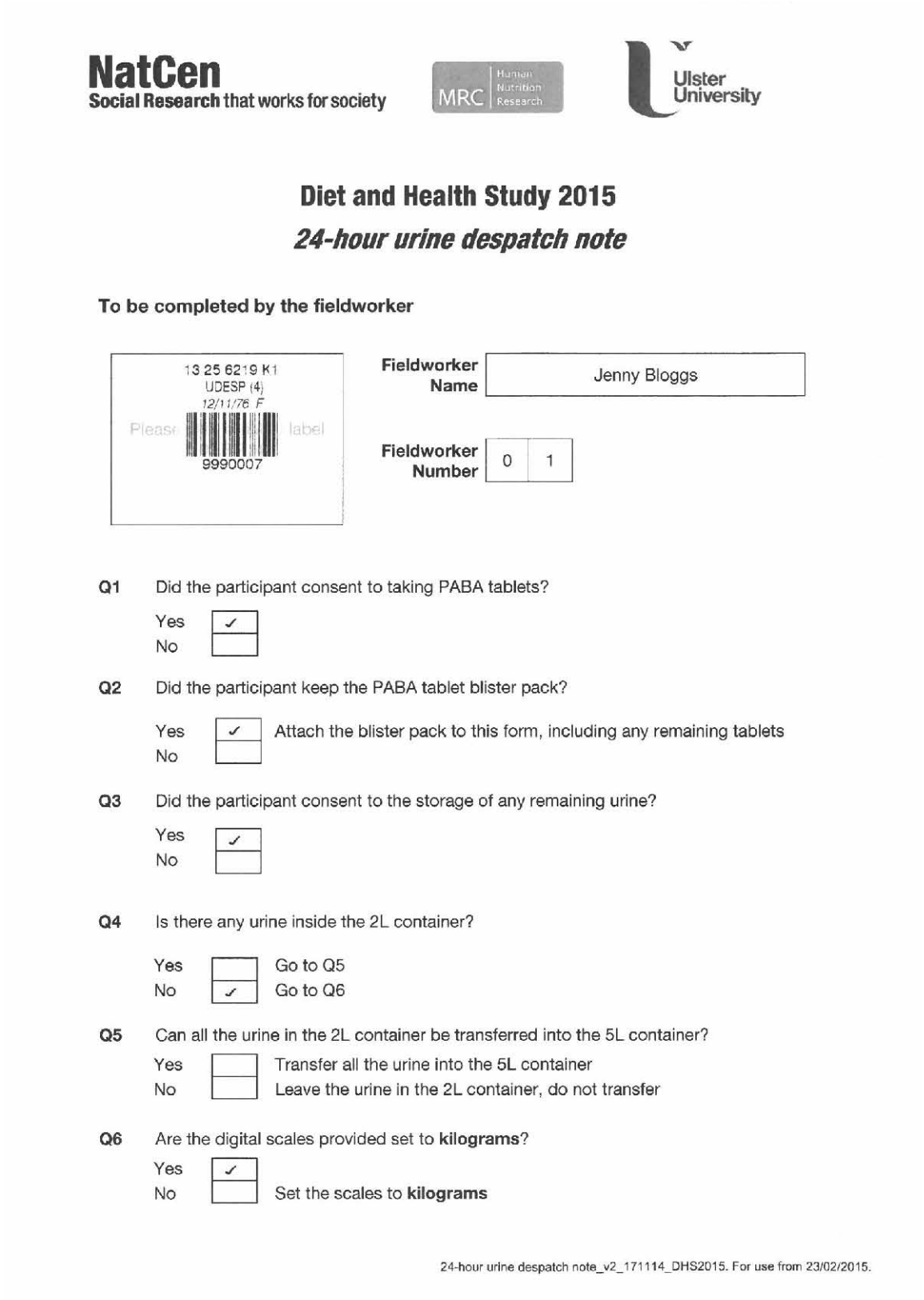
1	Bendroflumethiazide 2.5mg
2	Seven Seas pure cod liver oil capsule
3	
4	

Please give this form to the fieldworker, along with your urine sample and silver PABA tablet packaging. The fieldworker may ask you to confirm some of the details you have recorded.

Many thanks for taking part in this study!

As a token of our appreciation the fieldworker will give you a £15 gift card for completing this study.

Appendix D. Completed 24-hour urine despatch note



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MRC Human Nutrition Research

Ulster University

Diet and Health Study 2015

24-hour urine despatch note

To be completed by the fieldworker

13 25 6219 K1
UDESP (4)
12/11/76 F
Please label
9990007

Fieldworker Name Jenny Bloggs

Fieldworker Number 0 1

Q1 Did the participant consent to taking PABA tablets?

Yes ✓
No

Q2 Did the participant keep the PABA tablet blister pack?

Yes ✓ Attach the blister pack to this form, including any remaining tablets
No

Q3 Did the participant consent to the storage of any remaining urine?

Yes ✓
No

Q4 Is there any urine inside the 2L container?

Yes Go to Q5
No ✓ Go to Q6

Q5 Can all the urine in the 2L container be transferred into the 5L container?

Yes Transfer all the urine into the 5L container
No Leave the urine in the 2L container, do not transfer

Q6 Are the digital scales provided set to **kilograms**?

Yes ✓
No Set the scales to **kilograms**

24-hour urine despatch note_v2_171114_DHS2015. For use from 23/02/2015.

Q7 **5L container:** ☑ Tick this box if there is urine in the 5L container

- Weigh the urine a **first time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

2	8	2	**kg**

- Weigh the urine a **second time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

2	8	1	**kg**

- If the first and second weights differ by more than 0.02kg, weigh the urine a **third time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

		kg

If NO urine in 2L container: go to Q9

Q8 **2L container:** ☐ Tick this box if there is urine in the 2L container

- Weigh the urine a **first time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

		kg

- Weigh the urine a **second time** following protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

		kg

- If the first and second weights differ by more than 0.02kg, weigh the urine a **third time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

		kg

Q9 **Using the 5L container only,** mix the urine thoroughly by inverting / rotating 20 times before sub-sampling. **Fill 2 urine monovettes using the extension tubes** and discard the remaining urine and equipment as per instructions provided.

Please use the packaging provided and post the following items to HNR:

• Completed 24-hour urine collection sheet	• Filled urine monovetes
• Completed 24-hour urine despatch note	• PABA tablet blister pack, including any remaining tablets

24-hour urine despatch note_v2_171114_DHS2015. For use from 23/02/2015.