The NIHR Southampton Biomedical Research Centre (BRC) has a tight quality assurance system for the writing, reviewing and updating of Standard Operating Procedures. As such, version-controlled and QA authorised Standard Operating Procedures are internal to the BRC.

The Standard Operating Procedure from which information in this document has been extracted, is a version controlled document, managed within a Quality Management System. However, extracts that document the technical aspects can be made more widely available. Standard Operating Procedures are more than a set of detailed instructions; they also provide a necessary record of their origination, amendment and usage within the setting in which they are used. They are an important component of any Quality Assurance Framework, but in themselves are insufficient and need to be used and interpreted with care.

Alongside the extracts from our Standard Operating Procedures, we have also made available here an example Standard Operating Procedure and a word version of a Standard Operating Procedure template. Using the example and the Standard Operating Procedure template, institutions can generate their own Standard Operating Procedures and customise them, in line with their own institutions.

Simply offering a list of instructions to follow does not assure that the user is able to generate a value that is either accurate or precise so here in the BRC we require that Standard Operating Procedures are accompanied by face-to-face training. This is provided by someone with a qualification in the area or by someone with extensive experience in making the measurements. Training is followed by a short competency assessment and performance is monitored and maintained using annual refresher sessions. If you require any extra information, clarification or are interested in attending a training session, please contact Dr Kesta Durkin (k.l.durkin@soton.ac.uk).

This document has been prepared from Version 2 of the BRC Standard Operating Procedure for obtaining breath samples. It was last reviewed in October 2015 and the next review date is set for October 2017. The version number only changes if any amendments are made when the document is reviewed.

# NIHR Southampton Biomedical Research Centre

# Procedure for OBTAINING BREATH SAMPLES

# BACKGROUND

There are numbers of non-invasive tests available to assess the function of organs in the body, for example the liver and pancreas. These investigations involve collecting substances that are excreted by the body following the ingestion of a compound – one that is usually modified by the addition of a tracer of marker which is released by a defined physiological or metabolic process. If the test substrate is a form of fat that requires digestion by pancreatic lipase, then the hydrolysis of the fat and subsequent oxidation of the absorbed fatty acid, releases the tracer on the breath and the extent of excretion reflects pancreatic function. Expired breath contains air that has encountered different surfaces of the lung, and therefore different levels of gas exchange will have occurred. The air involved in gas exchange in the base of the lungs will be expired last. It is important to collect this end expiratory breath in the breath samples. Breath samples will then be analysed by mass spectrometry.

## PURPOSE

To ensure the safe and accurate collection of end of expiratory breath samples. The methods described in this procedure include using either a) a drinking straw, or b) the "flute method", by blowing across the tube and capturing end tidal breath. These methods of collecting breath samples have been shown to be effective (i.e. are associated with collecting a sample that contains sufficiently high amounts of carbon as carbon dioxide for analysis).

## SCOPE

This procedure applies to all staff involved in collecting breath samples for analysis by mass spectrometry.

## RESPONSIBILITIES

It is the responsibility of all staff involved in the collection of breath samples for analysis by mass spectrometry to read and follow this procedure.

#### PROCEDURE

- 1. The breath samples must be collected in tubes (non-evacuated exetainers). Label the tubes appropriately (i.e. patient I.D., date, time, sample number, breath collector's name).
- 2. Store the tubes in order, in a rack to allow ease of identification.
- 3. For each time point specified in the study, take three breath samples in 3 separate tubes.
- 4. Firstly someone (researcher, measurer) needs to demonstrate the procedure of blowing into a tube so that it is made clear to the participant what they are required to do. See sections A and B for procedures for individual sample collection methods.
- 5. At the time of the breath sample, remove the lids from the three tubes for the appropriate time point. The first three samples collected will be baseline measurements, given prior to administration of the test meal.

#### A) If using the "drinking straw" method:

- 1. Place a drinking straw into the first tube.
- 2. Ask the participant to take a breath and then to partially exhale.
- 3. Then ask the participant to blow the remainder of the breath through the drinking straw into the tube in a continuous stream of breath.
- 4. At the end of the breath, remove the straw quickly and slide the lid onto the tube in a single motion and then tighten to secure.
- 5. Repeat the procedure for the next 2 tubes of the same time point.
- 6. Replace the tubes in the rack in a place that indicates that they now contain samples.

#### B) If using the "flute" method:

- 1. Ask the participant to take a breath and blow in a single continuous exhalation across the top of the tube, creating a whistling sound so that air enters the tube
- 2. At the end of the breath, remove the straw quickly and slide the lid onto the tube in a single motion and then tighten to secure.
- 3. Repeat the procedure for the next 2 tubes of the same time point.
- 4. Replace the tubes in the rack in a place that indicates that they now contain samples.