This document is for guidance on the collection of biological samples that have been granted ethical approval under CUREC procedures.

Certain research involving the taking of samples that consist of, or include, cells (considered to be *‘relevant material’ by the Human Tissue Act), requires the approval of an NHS Research Ethics Committee.

Where human tissue is held in storage for less than 7 days pending transfer to a Human Tissue Authority (HTA) licensed establishment, the storage is considered incidental to transportation and an HTA licence/ethical approval is not required. An example would be where tissue for use in research is collected across a number of sites and batched before being sent to an establishment licensed by HTA for storage for research. Where this applies, studies may be reviewed by CUREC.

Where human tissue is being held whilst it is processed with the intention to extract DNA or RNA, or other liquid/subcellular components that are not relevant material (i.e. rendering the tissue acellular), such studies may be reviewed by CUREC, provided the processing takes place within 7 days and before any component of the sample is used for research.

If human tissue containing cells is used for any research purpose, whether within 7 days or not, it will require NHS ethics review rather than CUREC review. Advice on applying to the National Research Ethics Service, for review by an NHS Research Ethics Committee, is available from the University's Clinical Trials and Research Governance team.

**Brief outline of nature and purpose of procedure**

This policy covers the collection of samples of urine, stools or saliva that are collected in projects where there is a need to sample DNA, or to measure levels of hormones, gut microbiota, or other physiological indicators, and

- where the participants are not recruited via the NHS
- where the study involves no deception.
- where the biological samples are rendered acellular prior to use in research (This is a requirement of the Human Tissue Act.)

**Training and sample collection**

Research staff should be given training in how to collect and/or analyse samples by an experienced researcher.

Saliva samples may be either taken by a trained researcher, or the participant is sent full instructions together with a saliva collection kit. Participants follow printed instructions when providing urine or stool samples (see attached examples).

**Risks to participants**

There are no risks to participants in providing saliva samples. For urine and stool samples, the main considerations are to
• ensure proper hygiene when samples are taken
• to do so in a way that minimizes embarrassment to participants

Risks to researchers

There is a theoretical risk of infection when analysing samples of biological material, or when collecting saliva samples. Projects involving biological samples should undergo a departmental Risk Assessment.

• Participants should be screened to exclude those who suffer from communicable diseases.
• Researchers who handle biological samples should undergo occupational health screening; this may lead to a recommendation that researchers be immunised against hepatitis B.
• Researchers who handle biological samples should clean hands with disinfectant soap or wipes before and after handling the samples, and wear latex or nitrile gloves at all times when handling samples (not vinyl gloves, as they do not protect against viruses). They should avoid use of sharps.
• The cooler will be labelled as containing biological samples.
• Stool samples should be handled in a microbiological safety cabinet, and working area should be cleaned with 1% Virkon after use.
• Storage and waste disposal procedures should be specified on a Risk Assessment form and comply with Departmental Policy.

Monitoring and reporting of adverse or unforeseen events

Adverse and unforeseen events should be reported to IDREC as well as to the Departmental Safety Officer.

Disposal

In research projects that have been granted ethical approval under CUREC procedures, biological samples must be destroyed within 7 days, according to Departmental Policy on waste disposal.
How to collect a urine sample

The researcher will give you a container and explain to you how to collect the urine sample.

You can collect a urine sample at any time of day. Urine is more concentrated the first time you urinate in the morning, so if you collect this sample it may give better test results. However, this isn’t usually necessary unless the researcher tells you to.

To collect a clean urine sample:

- wash your hands
- males should wash their penis
- females should wash their genitals, including between the labia (lips around the entrance to the vagina)
- start to urinate but don’t collect the first part of urine that comes out
- collect a sample of urine ‘mid-stream’ (see below) in a sterile screw-top container
- screw the lid of the container shut
- label the container with your name, date of birth and the date
- wash your hands thoroughly

If the researcher gives you any other instructions, you should also follow these.

What is a mid-stream urine sample?

A mid-stream urine sample means that you don’t collect the first part of urine that comes out or the last part. This reduces the risk of the sample being contaminated with bacteria from your hands or the skin around the urethra (tube that carries urine out of the body).

Storing a urine sample until you hand it in

If you can’t hand your urine sample in within an hour, you should keep it in the fridge at around 4C (39F). Put the container of urine in a sealed plastic bag first. If the urine sample isn’t kept in a fridge, the bacteria in it can multiply. This may affect the test results.

Ideally, your urine sample needs to be handed in and sent for testing within four hours. However, the researcher may still be able to use it after this time if it’s been kept refrigerated.

If you can’t hand your urine sample in immediately, find out how long it can be kept in the fridge. The researcher who requested the test will be able to tell you.
How to provide a stool sample (postal participants)

Kit contents: cardboard kidney dish, nitrile gloves, specimen tube, Royal Mail SafeBox.
You will also need: a plastic carrier bag for disposal.

Please provide a sample from the first bowel movement of the day.
Please avoid contaminating your stool sample with urine: urinate before collecting the stool sample.

1) Place the cardboard dish in the toilet bowl (or in your child’s potty). Use the toilet normally, so your stool falls into the dish.

2) Remove the dish from the toilet bowl and put on the gloves. Use the small spoon attachment on the lid of the specimen tube to remove a small sample from the middle of the stool. A heaped spoonful of stool is sufficient. Place the stool in the specimen tube and close the lid tightly.

3) Flush the remaining stool down the toilet. Place the dish and the gloves in a plastic carrier bag, tie it securely and dispose of the bag with your normal household waste.

4) Following the instructions on the SafeBox, wrap the sheet of absorbent material around the specimen tube and seal the wrapped tube in the plastic zip-lock bag.

5) Wash your hands thoroughly with warm water and anti-bacterial soap; pat dry.

6) Put the zip-lock bag into the SafeBox. Fold your completed questionnaire and signed consent form and put them into the SafeBox, then follow the instructions to seal the package. Post the SafeBox in any post box (you do not need to add any stamps). If you will not be able to post the SafeBox within two hours of taking the sample, please refrigerate it until you can post it. If you do not want to put the sample in your refrigerator, fill an unwanted cardboard or plastic tub with ice cubes, put the sample inside and store in a cool place.
How to provide a stool sample (collection participants)

Kit contents: cardboard kidney dish, nitrile gloves, specimen tube, 2 zip-lock bags, cardboard container with lid.
You will also need: a plastic carrier bag for disposal.

*Please provide a sample from the first bowel movement of the day.*
*Please avoid contaminating your stool sample with urine: urinate before collecting the stool sample.*

1) Place the cardboard dish in the toilet bowl (or in your child’s potty). Use the toilet normally, so your stool falls into the dish.

2) Remove the dish from the toilet bowl and put on the gloves. Use the small spoon attachment on the lid of the specimen tube to remove a small sample from the middle of the stool. A heaped spoonful of stool is sufficient. Place the stool in the specimen tube and close the lid tightly.

3) Flush the remaining stool down the toilet. Place the dish and the gloves in a plastic carrier bag, tie it securely and dispose of the bag with your normal household waste.

4) Place the specimen tube in a zip-lock bag and seal. Place the sealed bag inside the second zip-lock bag and seal the outer bag.

5) Wash your hands thoroughly with warm water and anti-bacterial soap; pat dry.

6) Place the specimen in the cardboard container and put on the lid. Refrigerate the container with the stool sample until it can be returned to the researcher. If you do not want to put the sample in your refrigerator, fill an unwanted cardboard or plastic tub with ice cubes, put the sample inside and store in a cool place.