

# BEAM study Participant information sheet



## THE STUDY

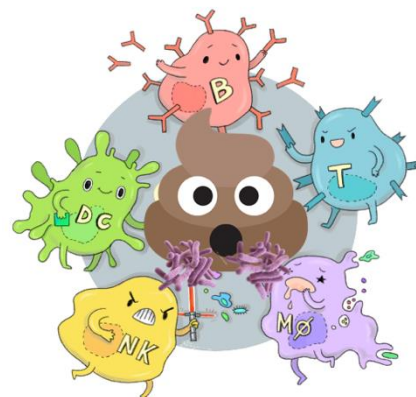
Our gut is home to trillions of different microbes that play a critical role in maintaining our health – what we call the microbiota. These microbes help programme our immune system and help us to digest the food that we eat. Recent work suggests that the microbiota can be disturbed or changed by different factors such as diet and certain medicines like antibiotics. This has been linked to an increased risk of developing diseases, e.g. inflammatory bowel disease and allergies. However, there have been some exciting studies showing that different types of gut bacteria can be used to improve health outcomes.

To build on these studies, we would like to look at women within the ages of 30-60 years to understand how the gut microbiota can affect breast health. The study aims to characterise a healthy microbiota ‘signature’ that may allow us to develop new therapies in next stage studies.

If you decide to take part in this study, we wish to collect the following at these time points:

- 4 faecal (stool) samples for one year.
  - We will give you a collection kit. The kit makes it easier to collect samples in a hygienic manner.
  - We will send you the collection kits to your *home address* or give them to you if you visit Norfolk and Norwich University Hospital (NNUH).
  - You can then return the sample to us by pre-paid post, so after collecting your sample you can put it in the post yourself.
  - After the 4 samples, we may ask you for 2 additional optional samples.
- Blood samples, whenever you come to NNUH where blood may be drawn.
  - We request you to donate an extra vial of blood when going in and blood may be taken.
  - At other times when you may come to NNUH, but no blood is drawn, we request a separate vial of your blood for our study. *This sample is completely voluntary, and your care will not be affected if you choose not to provide a sample.*
- Tissue samples, only if biopsies/surgery occurs.
  - We request to use the left-over tissue once your tests have been completed.

Faecal samples give a snapshot of your microbiota at that moment in time. Your microbiota will change according to your diet, exercise and any treatment regime you may undergo in the future. If you choose to participate, we will also ask you to do an online questionnaire to see how different lifestyle and diet choices may link to the gut microbiota profiles. Blood allows us to see what your immune system is doing throughout the body. We would also like to analyse any left-over surgical tissue (if you have surgery), so we can also look at immune cells in different types of tissue and link this to gut microbiota profiles. To do this, we need your permission and signed consent.



Adapted from: Dish on Science  
<http://thedishonscience.stanford.edu/>



## CAN YOU TAKE PART IN THIS STUDY?

Should you be interested in taking part in this study we ask if all these statements apply to you.

- Are you above the age of 30?
- Are you below the age of 60?
- You have not had cancer of any type before given this sheet.
- You have not had any antibiotic treatment (from the GP or Hospital) 3 months before given this sheet.

If you have answered YES to all of these, you are eligible for the study. Should you be uncertain please do not hesitate to ask.

## HOW WILL THE STUDY TAKE PLACE?

*The decision to participate in this study is entirely up to you.* If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. This study collaborates with the tissue bank: Norwich Research Park (NRP) BIOREPOSITORY. The original consent form will be stored by your hospital and a copy of the form will be sent to the NRP BIOREPOSITORY. Upon request you can also keep a copy for your records.

We will give or post the faecal collection kit to you or your home address, where you can collect your sample and post it back to the researcher. The kit has been pre-paid. We also ask if you could do a 20-minute online questionnaire for us that gives more information about your microbiota profile. If for any reason, you may have blood drawn at the hospital we would like to ask for an additional vial or ask a voluntary donation if no blood is drawn. **This is optional, and your care will not be affected if you say no.** If you for any reason may have to undergo surgery, we would ask for any left-over surgical tissue to be used for analysis.

## POTENTIAL RISKS AND BENEFITS

We do not anticipate any risks when partaking in this study.

## PATIENT'S RIGHTS AND CONFIDENTIALITY

Please note that your participation in this study is optional. **The decision to participate is entirely your own choice and should you choose not to participate it will not affect the treatment you would normally receive.** *You will not benefit financially nor receive compensation when participating in this study either.* Any publication that arises from this study may be made available to you upon request. You have the right to withdraw without giving a reason during the study at any time. The staff at NHS do not benefit from your participation in this study, so if you choose not to participate your care will not be affected. **Should you choose to withdraw or have any questions, please contact the NRP BIOREPOSITORY (phone number: 01603 289221 or email: [biorepository@nnuh.nhs.uk](mailto:biorepository@nnuh.nhs.uk)).**

Throughout this study sensitive data (name, address etc.) will remain anonymous to the researcher analysing your samples. Prior to sending the samples to the researcher, staff from the NRP BIOREPOSITORY will anonymise your data. From that point onwards, you will be identified by a unique number that cannot be traced back to you by the researcher or anyone working in this study. Members of staff from the Biorepository will need access to your clinical notes. This provides data relevant to your donated samples. However, as with the samples this will be provided anonymously to the researcher.

