**** 

 **PLAQARD: PLAQ**ue **A**s a **R**eservoir for *C.****D****ifficile*

Participant Information Sheet And Informed Consent Document

for non-cdi VOLUNTEERS

We invite you to take part in this research study

* Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
* Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
* You are free to decide whether to take part in this research study. If you choose not to take part, this will not affect any care you receive in the future.
* Ask us if there is anything that is not clear or if you would like more information.
* Thank you for reading this information. If you decide to take part, you will be given a copy of this information sheet and your signed consent form.

Important things that you need to know

* We want to find out how the presence and amount of *Clostridioides difficile* in the mouth of someone who suffers from a *C. difficile* infection (CDI), compares to you, someone without CDI, in order to learn more about the disease.
* If you agree to take part in this study, you will be asked to give oral samples of saliva and plaque, as well as answer some questions about your background and demographic.
* The bacteria in these samples will have their DNA extracted and analysed to determine the amount of *C. difficile* present.
* This study is sponsored by the University of Leeds and is coordinated by the Dental Translational & Clinical Research Unit (DenTCRU) at the University of Leeds, part of the NIHR Leeds Clinical Research Facility, in collaboration with the Division of Oral Biology and the Leeds Teaching Hospitals Trust (LTHT).
* The study will take place at the Dental Clinical Research Unit, situated within the Leeds Dental Institute.
* The study consists of one appointment where if you wish to take part, you will be consented to the study, screened to make sure you are eligible to participate, and finally give saliva and plaque samples.
* None of the sampling methods should be painful or cause any damage to your mouth.

Contents

1. Why we are doing this study
2. Why am I being asked to take part?
3. Do I have to take part?
4. What will happen to me if I take part?
5. Is it safe?
6. What are the benefits and disadvantages of taking part?
7. How will we use information about you?
8. What do I do if I have any concerns?
9. More information about taking part
10. Where can I get more information?

How to contact us

If you have any questions about this study, please contact a member of the PLAQARD study team:

Anna Nielsen

Research Dental Nurse & Study Coordinator

Tel: 0113 34 36156

Dental Translational & Clinical Research Unit (DenTCRU),

The Worsley Building, Rm 6.090,

Clarendon Way,

Leeds, LS2 9LU

Email: dentcru@leeds.ac.uk

1. Why we are doing this study

*Clostridioides difficile* (*C. difficile*) is a common infection-causing bacteria of the gut, producing toxins capable of causing severe damage to the colon. Up to 30% of patients experience relapses, which is costly in suffering for the patient and in expenditure to the NHS.

Periodontal disease, also known as gum disease, involves a significant build-up of harmful microbes that affect both the mouth and overall health. It is usually caused by poor tooth brushing and flossing habits that allow plaque—a sticky film of bacteria—to build up on the teeth.

The severity of periodontal disease is linked to the amount of dental plaque and the number of bacteria present. Early studies show that 79% of people with severe gum disease have *C.* *difficile* in their mouths.

We want to find out if dental plaque might serve as a hiding place for *C.* *difficile* and if there is a possibility that *C.* *difficile* can stay in dental plaque and move to the gut, leading to recurring infections. To do this, this study will look at the presence and abundance of *C. difficile* in the oral samples taken from participants who suffer from *C. difficile* infection (CDI) and compare them to those who don’t.

1. Why am I being asked to take part?

You are being asked to take part in this research study because you are CDI negative, and you have volunteered yourself as a potentially eligible participant. We are planning to enrol up to 40 individuals in the study (20 people with CDI and 20 without).

1. Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. The original consent form will be stored by the Dental Translational and Clinical Research Unit (DenTCRU) at the University of Leeds.

If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you may receive in the future.

1. What will happen to me if I take part?

First, we need to make sure that you are suitable for this study, and it is safe for you to take part. To do this we will need to ask you some screening questions.

During screening, you will be asked to sign a consent form, which you will be given a copy of. You will be asked questions about your demographic information (such as age, sex and ethnicity) and medical history relating to any previous *C. difficile* infections.

If the screening questions confirm that you can take part in the study and you are happy to continue, you will be asked to provide oral samples of plaque and saliva. An instruction document demonstrating the sample collection process will be provided to guide you to be able to collect these samples yourself, although a research dental nurse will be there to provide support with this if required.

**Saliva sampling:**

Unstimulated saliva will be collected by gently spitting into a sample collection tube as often as you can over a 5-minute period. 3-5 mL will be the target amount, although 1 mL would be satisfactory.

**Plaque sampling:**

Dental plaque will be collected with soft-ended dental micro brushes using a gentle sweeping motion over gum line or plaque affected tooth surface. The used micro brush will then be placed immediately into a separate sample collection tube containing a solution to preserve the sample. You will repeat this four times. Single use, disposable hand mirrors will be used to help see where to target and the dental nurse will verbally guide to areas where plaque is present. Written instructions on how to collect plaque will also be provided and the dental nurse can support with this if required.

Once the sample collection is complete, you have concluded your participation in the study.

1. Is it safe?

All instruments and materials used in this study will be sterile and single use. No part of the study sampling procedures are likely to cause any harm to you.

Sample collection is considered a non-invasive method; therefore, any risk is minimal. Mild gingival irritation or slight bleeding upon plaque collection may potentially occur, but this is no different from what can happen during normal toothbrushing.

1. What are the benefits and disadvantages of taking part?

**Benefits:**

There is no direct benefit for taking part, as this study is purely observational in nature. However, research does deliver wider benefits to society and potentially to those with conditions like CDI. Some indirect benefits might be foreseeable, like the satisfaction of helping professionals understand this illness better and increasing your own understanding of dental hygiene. This study could also instigate further research, which could have long-term social impact potential.

**Disadvantages:**

This appointment will take up some of your time, we predict up to an hour to complete the visit, but we will aim to take up as little of your time as possible.

There is a possibility that there will be no significant finding during this study about *C. difficile,* but this will not have a direct impact on you*.*

1. How will we use information about you?

We will need to use information from you for this research study. This will include:

* Your name
* Contact details
* Date of birth
* A brief medical overview in relation to any previous *C. difficile* diagnosis.

People will use this information to do the research or to check the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data and samples will have a code number (called study ID number) instead. This is a form of ID label which does not identify you.

The University of Leeds is the sponsor of this research study. The University of Leeds is responsible for looking after your information. We will keep all information about you safe and secure by:

* Storing all data collected in locked cabinets and NHS/University of Leeds electronic systems.
* Storing a copy of your signed consent form in a locked cabinet within the secured offices of the Dental Clinical and Translational Research Unit (DenTCRU) at the University of Leeds.
* Making your data accessible only to members of the research team.

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 5 years.

The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep any information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

* From our leaflet (http://www.hra.nhs.uk/patientdataandresearch)
* By asking one of the research team.
* By sending an email to dentcru@leeds.ac.uk
* By ringing us on 0113 34 36156
* Through the University of Leeds Privacy notice for Research Participants: <https://ris.leeds.ac.uk/privacy-notice/> or by contacting the University of Leeds data protection office via email at dpo@leeds.ac.uk.

Alternatively you can find further information via the HRA website Patient Data and Research Leaflet:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to receive a summary of the published results, either by email or post, you can indicate this when completing your consent form or by contacting the research team using the contact details on the front page of this leaflet.

1. What do I do if I have any concerns?

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of the local research team members who will do their best to answer your questions. Every care will be taken during this clinical study to maintain your safety.

In the unlikely event you are harmed by taking part in this research study, compensation arrangements are in place. If you have grounds for legal action you may have to pay your legal costs. Any claims will be subject to UK law and must be brought in the UK.

If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from your hospital. Alternatively, you may contact your local Patient Advisory Liaison Office. If you were harmed by taking part in this research, University of Leeds indemnity applies where it has been negligent in the design or the management of the research. Clinical negligence indemnification will rest with the participating NHS Trust under standard NHS arrangements. For independent complaints you can contact the University of Leeds Sponsor Representative on governance-ethics@leeds.ac.uk.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

1. More information about taking part

Who is organising and funding the research?

This study is being sponsored by the University of Leeds in collaboration with the Leeds Teaching Hospitals Trust. The study is funded by the National Institute for Health and Care Research (NIHR) Leeds Biomedical Research Centre.

**Who has reviewed the study?**

This study has been designed and reviewed by experts who felt this study to be of relevance and importance to people experiencing recurring *C. difficile* infections. The Study has been reviewed by NHS Health Research Authority, East Midlands - Leicester Central Research Ethics Committee and the Research and Innovation department situated within the Leeds Teaching Hospitals Trust.

What will happen to any samples I give?

Your samples will be transported to laboratory facilities within the University of Leeds and will be processed for storage as soon as possible after they have been collected. The samples will be labelled using your study ID number, so that they will be code linked.

Bacterial DNA will be extracted from the saliva and plaque samples you provide, and the amount of *C. difficile* DNA will be determined. A portion of the extracted bacterial DNA may also be tested to identify better ways of measuring levels of *C. difficile* in saliva or dental plaque. This could be useful to support future studies in this field. Fully anonymised extracted DNA samples may be sent to collaborating companies, including outside of the UK, to do comparative analysis as part of this study.

All samples are expected to be used but if any remain, these will be stored until the end of study and destroyed as per local practice in the University of Leeds. No original samples will be retained beyond the end of the study.

If you withdraw from the study, it may not be possible to withdraw samples already collected as these may have been processed and analysed together with other samples collected from the other participants in the study.

Your samples will **not** be used for commercial purposes.

Will any genetic tests be done?

The tests used to assess the bacteria in your mouth are a type of genetic test, but only bacterial DNA will be processed as part of the study.

1. Where can I get more information?

If you have any further questions about this condition or research studies, please discuss them with the research team.

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) has published a booklet entitled ‘Understanding Clinical Trials’.

Contact UKCRC:

Tel: 0207 670 5452

Website: [www.ukcrc.org](http://www.ukcrc.org/)

Another source of independent advice or support is the Patient Advisory Liaison Service (PALS):

Tel: 0113 2066261

Email: patientexperience.leedsth@nhs.net

Website:<https://www.leedsth.nhs.uk/patients-visitors/patient-and-visitor-information/patient-experience/patient-advice-and-liaison-service-pals-and-complaints/>

Local organiser

If you want further information about the study, contact your local organiser/doctor/dentist whose details are given on page 1.

**Thank you for taking the time to consider taking part in this study.**

****  

|  |  |
| --- | --- |
| Participant ID:  | Initials:  |
| Date of Birth:  |  |
| IRAS number: **345631** | Principal Investigator: **Dr F. McGill** |

**PLAQARD: PLAQ**ue **A**s a **R**eservoir for C. ***D****ifficile*

**NON-CDI VOLUNTEER PARTICIPANT CONSENT FORM**

***Please initial each box***

1. I confirm that I have read and understand the information sheet dated \_\_\_/\_\_\_/\_\_\_\_\_ (version \_\_.\_\_) for the above study. I have had the opportunity to ask questions and these questions have been answered.

2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my legal rights being affected. I understand that even if I withdraw from the above study, the data and samples collected from me will be used in analysing the results of the study. I understand that my identity will remain code linked.

*3.* I understand that the only samples to be retained beyond the study duration will be bacteria grown from my saliva and plaque for ethically approved future research purposes.

4. I agree for fully anonymised DNA extracted from my samples to be sent to external collaborators (potentially outside the UK) for comparative bacterial analysis as part of the study.

5. I understand that data collected during the study may be looked at by authorised individuals from the research team, regulatory bodies, or Sponsor in order to check that the study is being carried out correctly.

6. I agree to allow any information or results arising from this study to be used for healthcare and/or to support further medical research upon the understanding that my identity will remain anonymous wherever possible.

7. I agree to a copy of this Consent Form being sent to the Dental Translational and Clinical Research Unit (University of Leeds).

8. I agree to take part in the study.

9. I would like to receive a summary of the published study results and agree for the research team to collect my contact details for this purpose.

 *Please initial your box of choice:*  **Yes No**

**Participant:**

Signature…………………………………………………………………………………

Name (block capitals)……………………………………………….……………………

Date………………………………………………….……………………………………

**Investigator:**

I have explained the study to the above named participant and he/she has indicated his/her willingness to participate.

Signature…………………………………………..……………………………………

Name (block capitals)……………………………………………….…………………

Date………………………………………………….……………………………………

(1 copy for participant; 1 copy for medical notes; Original stored in Investigator Site File)