

# Your Treatment INFORMATION

**Research**

# RESEARCH

## Study Consent Documents

Assessing current clinical concepts in dental practice, IRAS 297799

### **This Informed Consent Form has two parts:**

1. Patient Information (to share information about the research with you)
2. Consent Form (for signatures if you agree to take part)

Principal Investigator: Colin Campbell

Organisation: The Campbell Clinic

Proposal: To conduct research regarding current clinical concepts in dental practice.

## Patient Information

Version: 6.0

Date: 6.4.26

## Invitation & brief summary

The Campbell Clinic are developing a number of studies aimed at assessing current clinical practice in dentistry, including treatment relating to dental implants, crowns and orthodontics. This will not involve any changes to your planned care.

We (The Campbell Clinic) would like to invite you to take part in these studies by giving consent for us to collect and store anonymised data from your clinical records acquired as part of your routine treatment. This data will be used for research purposes only. Everyone involved will keep your data safe and secure, and we will follow all privacy rules. We will make sure no one can identify you from the reports you write.

This information sheet gives you more information about data storage and use to help you decide whether to take part. You have been sent this form to read in advance of your next appointment, when a member of the team will go through the consent form with you and answer any questions you may have. If you choose to give your consent, this will be taken digitally, and a copy will be available to you in your Patient Portal by email. Please feel free to discuss this with others, and remember that you are not obliged to participate; this will not affect your treatment.

If you have further questions, you can contact us on: 0115 9823913 or email [info@campbell-clinic.co.uk](mailto:info@campbell-clinic.co.uk)

# SECTION 1: WHAT IS INVOLVED?

## Purpose of the Studies

To investigate current best practices in implant dentistry and other aspects of dentistry at The Campbell Clinic in order to study patient satisfaction and long-term outcomes.

Studies will look at different stages of implant treatment, including the techniques used in implant surgery, implant maintenance and hygiene, short-term and long-term outcomes, and patient satisfaction. Other dental treatment provided at The Campbell Clinic, such as complex extractions, crown and bridge restorations, orthodontics, and any treatment involving conscious sedation, may also be studied.

This work will help us to continuously improve the service we deliver, understand the needs and expectations of our patients, and provide evidence to support clinical and patient treatment decisions.

## Participant Selection

We are inviting all adults patients who attend The Campbell Clinic to participate in data collection and storage of data.

## Voluntary Participation

Your participation in this project is entirely voluntary. Your choice of treatment remains a decision made by you, and any clinical guidance offered is not influenced by these studies.

Whether you choose to participate or not, the quality of treatment you receive at the Clinic will not be affected. You may withdraw from the project at any time, and you do not need to give a reason for doing so. However, once a study which uses your anonymised data has been written up for publication, you will not be able to withdraw your consent for us to use your data for that particular study, but you may still withdraw consent for future uses of your anonymised data.

# SECTION 1: WHAT IS INVOLVED?

## Procedures and Protocol

In the practice, we will see you for routine appointments to review your care and ensure that your progress is normal. This is standard procedure. We may spend up to 10 minutes of additional time at these appointments to collect relevant data regarding your treatment. We may ask you to complete a short questionnaire regarding your treatment.

## Study Duration/ Long Term Follow-Up

Data will be collected during your routine appointments to assess your treatment progression. You will not need to make any additional visits to the practice. Please refer to your overall treatment consent documentation for full details of your treatment and appointments.

## Data Storage and Analysis

Data will be gathered from clinical notes, anonymised, and stored in a secure database on a server that is separate to clinical records. This data WILL NOT include or involve the use of personal or identifiable data. Gender and year of birth will be stored, as well as relevant information from your medical history. Studies will involve pooling and analysing data from groups of patients to make sure there is no risk of re-identification. This secure database, established in 2016, will be used for research purposes for a minimum of a further 5 years from 2026 (next review due 2031). The generic ethical approval of this database means that further ethical approval is not required for each us of the data.

# SECTION 2: ADDITIONAL INFORMATION

## Confidentiality

The information that we collect will be kept confidential. Information collected from you will be available to the practice research team, but we will not share your details with anyone outside of the practice. Any information stored and used by the research team will be anonymised (your name and any other identifiable details will be removed) and kept securely. We may choose to share anonymised information with others outside this practice in order to support continued development of best practice in dentistry.

## Sharing the Results and Research Transparency

We plan to share study findings through publications and presentations in order for health professionals and researchers to learn from this work. However, confidential information will not be shared - all data will be anonymous. You can see an up-to-date list of studies that use information derived from the database on our website. All publications will also be listed on our website, [www.campbell-clinic.co.uk/research](http://www.campbell-clinic.co.uk/research), and accessible via web links or on request to the practice. We would be happy to discuss and explain any findings with you.

## Right to Refuse or Withdraw

It is up to you to decide whether or not to take part in this project. If you do decide to take part, you may stop participating at any time you wish, and you do not need to give us a reason for this. We would then stop collecting your data for study purposes. We will continue to store and use any data collected up to the point of your withdrawal unless you request that we not do so. Withdrawing from the project will not affect your treatment, which is our priority.

## Benefits

Your participation will help us evaluate the service we provide to our patients and help us to maintain and improve the excellent standard of care we offer.

# SECTION 2: ADDITIONAL INFORMATION

## Risks

If you have any questions or concerns, you may ask them at any time, including once the study has begun. Contact us on 0115 9823913 or email [info@campbell-clinic.co.uk](mailto:info@campbell-clinic.co.uk).

## Who to Contact for Further Information

If you have any questions or concerns about aspects of this research, you may ask them at any time, including once the study has begun. Contact us on 0115 9823913 or email [info@campbell-clinic.co.uk](mailto:info@campbell-clinic.co.uk).

## Complaints

If you wish to complain about any aspect of the studies, then please address your complaints to the Practice Manager at The Campbell Clinic using the details above.



# SECTION 3:

## GDPR RESEARCH TRANSPARENCY STATEMENT

The Research Database will collect, store and use for research purposes anonymised information from your clinical records. We will only store information that we may need for research studies. This information will include:

- a unique ID number (your name and contact details will not be stored)
- your year of birth
- your gender (where stated)
- information from your medical history that may be relevant to your dental health (for example, smoking, diabetes)
- information from your dental records

The Campbell Clinic is the sponsor of this Research Database and is responsible for looking after your information. Everyone involved in the research database will keep your data safe and secure by:

- Limiting access to information which identifies you to those involved in your care, and to members of the Campbell Clinic research team who collect data.
- Using an assigned unique identification number in place of your personal details to anonymise data
- Storing your information in a database which is password-protected
- Storing the database on a server which is separate from patient records and which is password-protected
- Making sure no one can identify you from the reports we write.



# SECTION 3:

## GDPR RESEARCH TRANSPARENCY STATEMENT

Your data will not be shared outside of the UK.

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

After this 5-year ethical approval period ends, we may apply to extend this for a further 5 years. Should this not be the case, all data will be stored for a minimum of 5 years after project completion. Any proposed studies during that time would be subject to a new individual ethical approval application. After this period, the study data would be fully anonymised and securely archived.

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 information about you that we already have
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data.
- If we have already used your data in a publication this cannot be withdrawn.

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

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

- By asking one of the research team
- By sending an email to [info@campbell-clinic.co.uk](mailto:info@campbell-clinic.co.uk), FAO Research Data Protection Officer
- By ringing us on 0115 982 3913
- At [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)

This research database was originally approved by a Research Ethics Committee in 2016, and this approval was renewed in 2021 and then in 2026 for a minimum of a further five years.

If you think your data has been misused or stored insecurely, you have the right to file a complaint with the Information Commissioner's Office.

# SECTION 3:

## GDPR RESEARCH TRANSPARENCY STATEMENT

### THE CAMPBELL CLINIC STUDY CONSENT FORM

Version: 3      Date: 15.4.26

Title of project: Assessing current clinical concepts in dental practice v2.0.

Primary Investigator: Colin Campbell

Contact details: 0115 9823913

1. I confirm that I have read and understand the participant's information sheet dated 15.4.26 version 6.0 for these studies.
2. I have been given the opportunity to ask questions, and these have been answered to my satisfaction.
3. I understand my participation is voluntary, and I can withdraw at any time without giving a reason and without affecting my treatment.
4. I have been informed of and understand the purposes of the studies.
  
5. I understand that my patient notes may be looked at by researchers at the Campbell Clinic. I give permission for these individuals to have access to my records. Procedures for confidentiality have been explained to me.
6. I understand that my anonymised data may be used in future reports, publications, articles or presentations by the Campbell Clinic.
7. I understand that any information which could potentially identify me will not be used in published material.
8. I understand that information collected about me could be used to support other future studies and may be shared anonymously with other researchers outside of The Campbell Clinic.
9. I agree to participate in these studies as outlined to me in the Patient Information Sheet.

Participants Name  
Date  
Signature

TCC Health Professional Name  
Date  
Signature

This proposal has been reviewed by a Research Ethics Committee

Note – this consent form is available online for information only, research consent will be discussed in person at one of your appointments.

**T** 0115 9823 913

**E** [info@campbell-clinic.co.uk](mailto:info@campbell-clinic.co.uk)

**[www.campbell-clinic.co.uk](http://www.campbell-clinic.co.uk)**

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