STUDY CONSENT DOCUMENTS
Assessing current clinical concepts in dental practice v1.0

This Informed Consent Form has two parts:

- Patient Information Sheet (to share information about the research with you)
- 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 SHEET
Version……4.0…… Date……17.11.16……

## Introduction

The Campbell Clinic are developing a number of studies aimed at assessing current clinical practice in dentistry.

We would like to invite you to take part in these studies by giving consent for The Campbell Clinic to store anonymised data acquired as part of your routine treatment. This data will be used for research puposes. 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. Please feel free to discuss this with others and remember you are not obliged to participate; this will not affect your care.
**If you have further questions you can contact us on: 0115 9823913 or email info@campbell-clinic.co.uk**

## Section 1: What is involved

### Purpose of the studies

To investigate current best practice in implant dentistry and other aspects of dentistry at The Campbell Clinic. Studies will look at different stages of implant treatment, including: the techniques used in implant surgery, implant maintenance and hygiene, long term outcomes, and patient satisfaction. This work will help us to continuously improve the service we deliver, and provide evidence to support clinical and patient treatment decisions.

### Participant selection

We are inviting all adults who attend The Campbell Clinic to participate in 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.

### Procedures and Protocol

In the practice we will see you for routine appointments to review your care and ensure progress is as normal. This is standard procedure. We will spend approximately 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 consent documentation for full details of your treatment.**

**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** 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 reidentification. This secure database will be used for research purposes for a minimum of five years.

## 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**
We plan to share study findings through publications and presentations in order for others 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.

**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, although would continue to store and use data collected up to your withdrawal unless you request us not to. Withdrawing from the project will not affect your treatment, which is our priority.

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

**Risks**
This study does not involve any additional treatment over and above your routine care. Please refer to your patient information letter to remind you of the risks involved in your treatment. Please see the 'Confidentiality' section which discusses appropriate use and storage of confidential information.

**Who to contact for further information**
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 .

**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.

THE CAMPBELL CLINIC STUDY CONSENT FORM
Version.....1..... Date.....31.8.16.....

**Title of project: Assessing current clinical concepts in dental practice v1.0.**
**Primary Investigator: Colin Campbell**
**Contact details: 0115 9823913**

| | | Please Initial |
|---|---|---|
| 1. | I confirm that I have read and understand the participant information sheet dated 17.11.16, version 4.0 for these studies. | |
| 2 | I have been given 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 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 individuals 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. | |

Name of Participant Date Signature

Name of TCC Health Professional Date Signature

*This proposal has been reviewed by a Research Ethics Committee*

**Study Consent Documents**
**Assessing current clinical concepts in dental practice: IRAS 209906**
Non-notifiable, non-substantial amendment, May 2018 (GDPR) v.1.0

**Research Transparency Statement:**

The Campbell Clinic is the sponsor of the research arising from the Research Database based in the UK. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this database. This means that we are responsible for looking after your information and using it properly. The Campbell Clinic research database will keep identifiable (pseudo-anonymised) information about you for a minimum of five years.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw your research consent, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The Campbell Clinic will collect information from you and your medical records for this research database in accordance with our database management protocol. Our legal basis for processing your data is 'legitimate interests', and we will still ask for your consent to meet the common law duty of confidentiality.

The Campbell Clinic will use your name and contact details to contact you about the research database, to ask if you are willing to consent for your data to be stored, to make sure that relevant information about the database is recorded for your care, and to oversee the quality of the database. Individuals from The Campbell Clinic and regulatory organisations may look at your medical and research records to check the accuracy of the research. The people in The Campbell Clinic who will have access to information that identifies you will be people who need to contact you as part of your routine care, members of the research team who collect your data, or those who audit the data collection process. When the research team analyse the data, they will not be able to identify you and will not be able to find out your name or contact details.

This research database has been approved by a Research Ethics Committee for a minimum of five years, and is subject to an annual review process.

You can find out more about how we use your information at http://www.campbell-clinic.co.uk/research-nottingham.php or by contacting us at info@campbell-clinic.co.uk ; tel. 0115 9823913. The Data Controller is Colin Campbell, and the Data Protection Officer is Hayley Brown.

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