Optimizing 3-D printed dentures.

PATIENT INFORMATION SHEET

You have been invited to take part in a research study to improve the way we manufacture dentures. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and discuss it with others if you wish. Ask us if anything is unclear, or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

What is the purpose of the study?

There is a new way to manufacture dentures using a new technology called 3-D printing. This technology builds up very thin layers of materials one on top of another until an object is formed. We hope this new method will allow us to manufacture better dentures. To find out if the new way is better we must first standardize the way we construct the new dentures. The aim of this preliminary study is to determine which clinical procedures are the best way to construct high quality, 3-D printed dentures.

Why have I been chosen?

We wish to include patients who:

1. Have no natural teeth of their own
2. Need new dentures

Do I have to take part?

No, participation in this study is entirely voluntary. If you decide not to take part, your access to or provision of the dental care you receive will not be affected in any way. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

Before you take part in this study, you are given this Patient Information Sheet which you ask you to read in full. You are encouraged to ask as many questions as you would like. You can take as long as you need (at least 24 hours) to consider the information provided and consult with your dentist, family and friends as you wish.

If you agree to take part, we will ask you to sign a consent form and register you for the trial. Then the dentists in this Research Team will make 2 sets of dentures for you. One set of dentures will be manufactured in the normal way and the other set of dentures will be manufactured by the new method. At the third visit you will be asked to compare two different denture blocks to say which is the most comfortable. It is worth mentioning that apart from this assessment of the blocks at your third visit, there are no additional impressions nor are there any additional clinical procedures planned during the construction of the extra set of dentures.

Once the 2 sets of dentures have been made, you will be given both dentures and asked to comment on the comfort, stability and appearance of the dentures. You will be asked if you have a preference for either denture. You will then be asked to take away both sets of dentures for 2 weeks. After these 2 weeks, you will be asked again for your opinion of the dentures and specific questions about the stability, comfort and appearance of each set of dentures.

Finally you will be asked if you wish to improve the appearance of either set of dentures and if you would, we will offer to change the appearance of the dentures at the end of the investigation and ask you to give us feedback on the process.

How long does the research study go on?

The construction of any new dentures normally takes 6 visits. This research will take place during your normal visits; no extra visits are planned. However, there will be the extra denture to fit and we will be seeking your opinion and feedback, so we expect three appointments will be lengthened by between 15 and 30 minutes.

Unwanted effects of the dental procedure / dentures

All of the dental procedures that we will undertake to make your new dentures are routine, 'normal' dentistry. Sometimes new dentures need to be adjusted and we expect these "study" dentures may also need to be adjusted in the normal way.

At each visit your dentist will monitor the effect of the dentures on your mouth and will advise you if anything changes.

What are the possible disadvantages and risks of taking part?

It is usual for it to take a minimum of 6 visits to your dentist to construct dentures. In this study three visits of the normal clinic visits will take an extra 30 minutes.

What are the possible benefits of taking part?

You will be given 2 sets of dentures. You will keep both sets of dentures and can choose to use the best one to wear. Your participation will help in developing an evidence-based procedure for the benefit of people who need new dentures.

What if something goes wrong?

Every care will be taken in the course of this study. If you have a concern about any aspect of this study you can speak to your dentist or one of the other researchers who will do their best to answer your questions.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for the legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from this Hospital's information service and are available in the clinic.

What happens when the research study stops?

At the end of the study you will be able to keep both sets of dentures and can choose to use the best one. Once your participation in the study has finished, you will be referred back to your usual dentist.

Will my taking part be kept confidential?

The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

The local research site at the Dental School in Leeds/Manchester/Birmingham [delete as appropriate] will keep your name, and contact details confidential and will not pass this information to the University of Leeds. The local research site at the Dental School here in Leeds/Manchester/Birmingham [delete as appropriate] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from University of Leeds and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The University of Leeds will only receive information without any identifying information. The people who analyse the information at the University of Leeds will not be able to identify you and will not be able to find out your name, or contact details.

The local research site at the Dental School here in Leeds/Manchester/Birmingham [delete as appropriate] will keep identifiable information about you from this study for 5 years after the study has finished.

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 from the study, we will keep the information we have already obtained that is recorded against the research number (this is NOT identifiable information). If you withdraw we will remove identifiable information we hold locally from the research file.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way

that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

At all times, to safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about exactly how we use your information in the paragraph below or by contacting Dr T P Hyde on t.p.hyde@leeds.ac.uk.

How will my taking part in this study be kept confidential?

Within the local research site file, a Recruitment Log will record the unique study number allocated to you against your name, and personal details. Once you have signed the consent form and been allocated a study number, all subsequent paperwork will only identify you by reference to your unique study number, and your initials. Apart from the consent form you sign and the local recruitment log at each research site, no other study documentation will record your personal data or name.

The Consent form and the Recruitment Log will be securely stored in a locked 'Investigator Site File'. Each research site will maintain this File in a secure location. The other forms we will use to collect data are called 'Data Collection Sheets', they only contain your unique study number, and initials. The paper copies of these are also stored in the secure 'Investigator Site File'.

At each research site the paper copies of the Data Collection Sheets (which do NOT contain identifiable data) will be electronically scanned and stored, with password protected access, on a password protected computer in the secure research office adjacent to the Investigator Site File.

Each week the electronic copy of the Data Collection Sheets (which do NOT contain identifiable data) will be sent to the secure data storage at Leeds University. These files will be sent by encrypted e-mails; they do not contain your name.

In order to comply with international standards for research governance, your healthcare records may be inspected by authorised individuals from the research team or the University of Leeds (the study Sponsor) or the regulatory authorities to ensure that the study is being carried out correctly. When the study is complete the results may be published in a dental/medical journal, but no individual patients will be identified.

What will happen if I don't want to carry on with the study?

If you withdraw consent from further study procedures and/or follow-up, for this preliminary study, the sponsor will be informed and all identifiable data will be destroyed.

If you wish to withdraw from the study, but you wish to continue with the construction of new dentures, your dentist will arrange for you to continue your care elsewhere within the LDI.

What will happen to the results of the research study?

The results of this study will be used to inform this research team of the best way to make 3-D printed dentures. We will use the information from this study to design a future clinical trial of 3-D printed dentures. We may also report the results of the current study to other dental researchers at a research conference. We may publish the results of this study in a science journal. You will not be identified in any report or publication about this study.

Contact Details

If you have any further questions about your dental care or clinical studies, please discuss them with your dentist. If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organizations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org

Your contact telephone numbers:

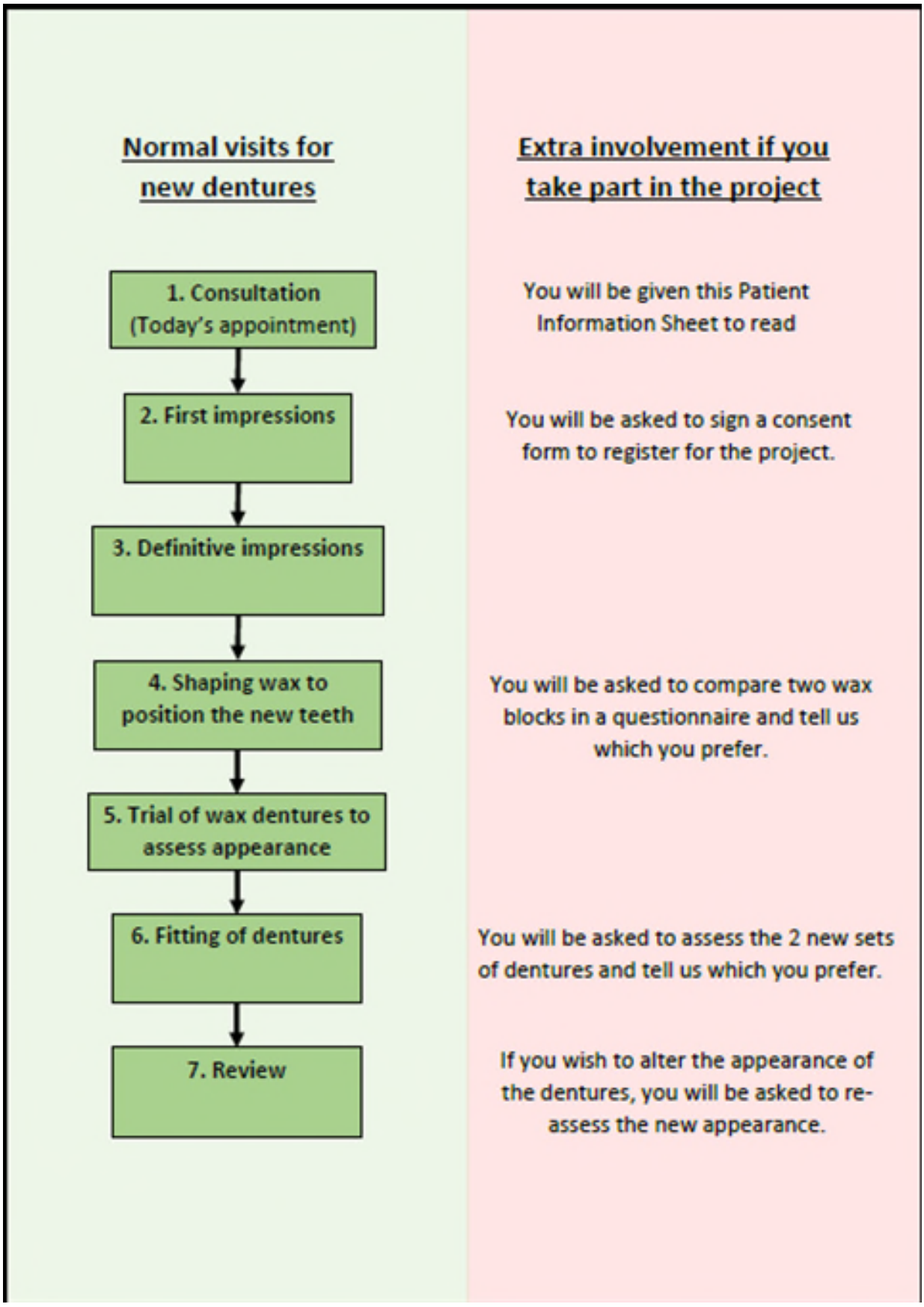
Delete this section and insert the contact details for each local research site:

Contact and contact details

Leeds contact: Dr T P Hyde on t.p.hyde@leeds.ac.uk

……

……


Normal visits for new dentures
Extra involvement if you take part in the project
1. Consultation (Today's appointment)
You will be given this Patient Information Sheet to read
2. First impressions
You will be asked to sign a consent form to register for the project.
3. Definitive impressions
4. Shaping wax to position the new teeth
You will be asked to compare two wax blocks in a questionnaire and tell us which you prefer.
5. Trial of wax dentures to assess appearance
6. Fitting of dentures
You will be asked to assess the 2 new sets of dentures and tell us which you prefer.
7. Review
If you wish to alter the appearance of the dentures, you will be asked to re-assess the new appearance.