University of CINCINNATI

UNIVERSITY OF CINCINNATI - MEDICAL
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: **3D Models for Mandibular Fracture Repair**	
PRINCIPAL INVESTIGATOR NAME: Deepak G. Krishnan, DDS, FACS	**PHONE NUMBER (24-hour Emergency Contact)** 513-584-7910
IRB: University of Cincinnati IRB (513) 558-5259 irb@ucmail.uc.edu	**SPONSOR:** **Investigator initiated**
PARTICIPANT NAME:	**DATE OF BIRTH:**

INTRODUCTION:

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. Your participation in this study is entirely voluntary. If you decide to participate, you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

WHY IS THIS RESEARCH BEING DONE?

The investigators will test the question that patients who underwent jaw surgery with a 3D model with have a shorter time in the operative room time than patient who didn't receive a 3D model.

The purpose of this study is to evaluate the ease of use, accuracy, and compatibility with current surgical approaches to re-work the current standards of care to include the use of on-site 3D model creation and surgical planning for treatment of jaw fractures.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you will be undergoing treatment for a jaw fracture.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the study just for the duration of your procedure.

The researcher may decide to take you off this research study at any time.

You may withdraw from the study at any time.

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

WHO IS CONDUCTING THE RESEARCH STUDY?

The study is directed by Dr. Deepak Krishnan at the University of Cincinnati Medical Center. The research will take place at the University of Cincinnati and the facilities of the affiliated health systems, UC Health, LLC and University of Cincinnati Physicians Company, LLC.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

We aim to obtain 50 procedures for each arm of the study (100 in total)
50: standard surgical procedures aided by use of 3D Printed model
50: procedures carried out by standard surgical repair for isolated mandibular fractures (No model)

WHAT IS INVOLVED IN THE RESEARCH STUDY?

We plan to conduct a randomized controlled trial on patients brought to either UCMC or UC HH OMS for treatment of jaw fractures. This study plans to determine whether the use of 3D models during surgery will minimize both OR time and costs. Subjects will be identified based off the initial physical assessments made by surgical specialists from OMS, Plastic Surgery, and ENT. Once the subjects are identified the research coordinator will conduct a screening of the patient to ensure they meet the inclusion/ exclusion criteria for the study and then randomize the patient into either normal standard of care for surgical repair of the fractured jaw or normal standard of care for surgical repair of the fractured jaw aided by a 3D printed model. Any chart reviewing will be conducted from existing electronic medical records maintained by UC Health EPIC and OMS Vision.

Following completion of the procedure, for the surgeons who received aide via the 3D model they will be asked to answer a brief Likert Scale survey outlining their thoughts how effectively or ineffectively the model assisted them. In addition to this information, if they feel the model increased efficiency saving time, they will be asked to state how much time they felt was saved. This time differential will be compared to current CPT codes for OR time to understand how much in operational costs were saved by utilizing the models.

The researchers will also collect some data about you such as gender, age, ethnicity, medical history, and your current condition from you and from your medical records.

All data will be stored on REDCap, a secure web-based application used for data collection. During data collection, the research coordinator will record the data directly into REDCap. All data acquired for the study will be de-identified and each participant will be assigned a study ID number.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

There are no risks related to the 3D printing. The physical model is generated from the medical images that have already been acquired, and the addition of the 3D printed model for those patients randomized to the 3D printing arm will be completely transparent. The following risks as described are general risks that the patient would assume with the study.

The potential risks involved in this study are routine for the planned surgery, which the patient would undergo regardless of their participation in the study. Overall, none of the risks involved are significant given their rarity, and almost all can be prevented with standard-of-care treatment. If complications arise, they can be managed directly by UC OMS team, which are the designated specialty service for such issues. Additionally, our location and association with University of Cincinnati Medical Center provides accessibility to any level of care or type of specialty in case of an unlikely emergency.

Increased OR Time
Prolonged operative time is associated with an increase in the risk of complications. For instance, an association between the duration of surgical procedures and complications such as surgical site infection, bleeding, blood clots, and tissue death has been reported in studies across various surgical procedures. Although complication rates differed, longer operative times correlated with a greater risk of complications.

There is a minor risk of loss of confidentiality of your information. You will be assigned a study ID number in the REDCap database and all identifying information will be removed. All your collection information, as well as procedural notes and medications, will be placed under this generated ID number. This de-identified patient ID number will be the only connection to you which is only known by members of the study team. The key linking your identity to the ID number will not be stored with the electronic data. Electronic data within this REDCap dataset will be located on a secure computer. The data will be stored on a password protected, secured computer, that is stored in a locked room within the oral and maxillofacial surgery department on UC Medical Center's campus.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may not be a direct medical benefit to you.

WHAT OTHER CHOICES FOR CARE ARE THERE?

You have the option not to participate in this study. You will continue to receive all standard care for your illness.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

You will not be provided with your individual results from this research study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

There are no additional costs from your participation in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will not be paid to participate in this study.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have, nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

WHAT IF YOU ARE AN EMPLOYEE WHERE THE RESEARCH STUDY IS DONE?

Taking part in this research study is not part of your job. Refusing to be in the study will not affect your job. You will not be offered any special work-related benefits if you take part in this study.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your medical and research records related to this study. Agents of the University of Cincinnati, and the monitor, the auditor, the Institutional Review Board (IRB), and other regulatory authorities will be granted direct access to your original medical and research records for verification of clinical trial (research study) procedures or study data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representative are authorizing such access. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.

Authorization to Use and Disclose Health Information

A federal regulation known as the Privacy Rule requires that the researchers get your written permission to use your health care information in this research study. If you sign this form, you are giving your authorization for the use and disclosure of your health information for research purposes. You do not have to give this authorization. If you do not give your authorization, you cannot be in the research study. However, if you are being treated as a patient here, you will still be able to receive care.

Who Will Use and Disclose My Health Information? The researchers will use your health information to conduct, review, and determine the results of the study. The researchers may also use your information to prepare reports or publications about the study. Your name will not appear in any report or publication without your permission.

Who Will Receive My Health Information? The following people or groups may receive your health information:

- Researchers who are conducting this study at other study centers

- The study sponsor or its representatives, including companies it hires to provide study-related services
- University of Cincinnati Institutional Review Board (IRB) or an outside external IRB reviewing the study
- Other compliance committees responsible for overseeing the research
- UC Health and UC hospital or clinic employees providing service or care to you
- Federal and State agencies, such as the U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others?
If the groups above share your health information with others, it will no longer be protected by the Privacy Rule.

Will My Authorization Ever Expire? Your authorization will not expire.

May I Take Back My Authorization? You may take back your authorization at any time by writing to the study doctor. If you take back your authorization, you will not be able to stay in this study. If you take back your authorization, the study team will not collect any new health information about you. Information that has already been collected may still be used and given to others. If you withdraw your authorization, no new health information will be collected unless you have a side effect related to the study.

May I Look at My Study Information? You may be able to look at and make copies of your health information collected for this study when the study is completed. Information that could identify you will be removed from the study data. The study data will not be used or shared for future research studies.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact the research coordinator at (513) 584-2094.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

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PARTICIPANT NAME:	**DATE OF BIRTH:**

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.
I give my consent to participate.

Signature of participant Date

PERSON OBTAINING CONSENT
I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Signature and Title of Person Obtaining Consent and Identification of Role in the Study | Date | Time