INFORMED CONSENT DOCUMENT

Project Title: University of Iowa College of Dentistry and Dental Clinics Data and Specimen Repository

Principal Investigator: Dr. Azeez Butali

Research Team Contact: Dr. Azeez Butali
                      (319) 335-8980

- If you are a teenager reading this document because you are being invited to be in this study, the word “you” in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.
- If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word “you” in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate.
- If you are acting as a witness for a subject that is unable to read the document (illiterate), you will be asked to sign this document indicating that you have witnessed that the subject was read the document and understands their involvement. The subject will also sign the document.

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in a data and sample repository because you are a patient or are accompanying a patient or a University of Iowa employee, retiree or student who receives care at the University of Iowa College of Dentistry and Dental Clinics, Muscatine Outreach Clinic, the University of Iowa Center for Disabilities and Development or the University of Iowa Hospitals and Clinics Department of Otolaryngology, The University of Iowa Hospitals and Clinics or you are a University of Iowa employee, retiree or student requesting to participate in the study. We will collect your clinical information (dental and medical), saliva, cheek, crevicular fluid (a small amount of fluid that is present between the
tooth and the gums surrounding the tooth), teeth and bone (if being removed) and tissue samples for future dental research purposes.

The purpose of this repository at the University of Iowa College of Dentistry and Dental Clinics is to have a central place to store clinical information (dental and medical), saliva, cheek, crevicular fluid, teeth and bone (if being removed) and tissue samples for researchers to use in the future to study and learn more about dental conditions and diseases. The overall goal is to find causes, better treatments, and ways to prevent health conditions and diseases. If we share your data and samples with outside researchers, we will remove your name and all personal identifiers. There may be certain circumstances where a University of Iowa researcher would need personal identifying information to adequately conduct a specific research project. In this instance, we would require the researcher to submit in writing a request of such and provide to our Biorepository governing committee their research project which has been approved by The University of Iowa’s Institutional Review Board. The Biorepository governing committee will carefully review the application and only provide the minimum necessary for the researcher to conduct their research project.

**HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 20,000 people will take part in this study conducted by investigators at the University of Iowa.

**HOW LONG WILL I BE IN THIS STUDY?**

If you agree to take part in this study, your direct involvement will be one visit lasting up to 30 minutes.

**WHAT WILL HAPPEN DURING THIS STUDY?**

Your study visit will take place in the clinics at the University of Iowa College of Dentistry and Dental Clinics, Muscatine Outreach Clinic, the University of Iowa Center for Disabilities and Development, the University of Iowa Hospitals and Clinics Department of Otolaryngology, The University of Iowa Hospitals and Clinics or the University of Iowa Employee Health Fair at the Field House.

A container will be used to collect your saliva in. It may take 30 minutes for the ideal amount of saliva to be collected, but most participants usually take about 5 to 10 minutes.

We will collect a sample of your saliva.

We will perform a cheek swab by rubbing a long cotton swab inside your mouth along your cheek.

We will collect gum tissue by forcefully rubbing a brush against your gums.
We will collect tissue, teeth and bone that are being removed.

If we require a saliva sample in addition to your teeth sample, we will either collect the sample prior to your extraction being completed or we will provide you with a saliva sample collection kit which will include instructions on collecting the sample and a self-addressed, stamped envelope in which to return the sample.

We will collect crevicular fluid by applying a paper strip against your teeth/gums or a syringe to withdraw the fluids around the teeth/gums.

We will store all these samples in the repository in addition to the following data collected from your University of Iowa College of Dentistry clinical system and University of Iowa Hospitals and Clinics health system medical records: comorbidities, full name, date of birth, age, sex, ethnicity, family health history, birth defects, genetic disease, oral disease, reason for visit, clinical and health medical record numbers.

**Genetic Research**
One purpose of the studies using this repository is to use the samples collected to look at how genes (DNA) affect health and disease. Genes are the instruction manual for the body. The genes you get from your parents largely determine what you look like and how your body behaves. Genes (DNA) can tell us a person’s risk for certain diseases and how he or she will respond to treatment.

What we learn about you from the samples will not be put in your clinical information (dental and medical).

**Genetic Information Nondiscrimination Act (GINA)**
A new federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information. Based on this new law, health insurance companies and group health plans are prohibited from requesting your genetic information that we get from this research. This means that they may not use your genetic information when making decisions regarding your eligibility for insurance coverage or the amount of your insurance premiums. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. The law also does not prohibit discrimination if you already have a manifest genetic disease or disorder.

**Tissue/Samples and Data Storage for Future Use**
As part of this study, we are obtaining clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples from you that we would like to store to study in the future. It will be stored for many years until the samples are used up or are no longer appropriate for use in research studies.
Specified administrators of the repository are the only individuals who will be able to link your identity with your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples.

Your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples will be stripped of identifiers (such as name, date of birth, address, etc.), labeled with an ID code, and stored in a repository (central storage place), a locked room in the UI College of Dentistry and Dental Clinics.

Qualified researchers who would like to gain access to clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples from the repository must submit their research proposals to the specified repository administrators who monitor and approve data and samples used through the repository. Specified repository administrators will carefully review the research proposals to ensure that the dental research project is worthy. Then, they will grant permission to researchers to utilize the repository.

Use of the samples in the future will be done without contacting you about any test or study.

The nature of the research in which your saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples may be used will vary but will always relate to dental research. Samples may be used for reading out all the genetic information (sequencing) and/or studies that show differences in the genetic information across the entire human genome (genome wide studies).

The tests we might want to use to study your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples may not even exist at this time. Therefore, we are asking for your permission to store your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples so that we can study those in the future. The future studies may provide additional information that will be helpful in understanding dental conditions and diseases, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples, but decide in the future that you would like to have the information and samples removed from future research, you should contact Dr. Azeez Butali at (319) 335-8980. However, if some research with your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples have already been completed, the information from that research may still be used.
WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

There are no known risks with giving a saliva sample.

Participation in the repository does involve the possible risk that information about your health might become known to outside individuals. However, we have made efforts to minimize this risk and to protect your confidentiality by removing personal identifiers from your clinical information (dental and medical), saliva, cheek, crevicular fluid, tissue, teeth and bone (if being removed) and gum tissue samples before allowing outside researchers to use it in studies. Researchers at The University of Iowa Hospitals and Clinics will only be provided the minimum necessary to conduct their approved research project. The information provided may contain personally identifying information.

When we use a brush against your gums, you may feel tingling a little bit. If you feel pain or have questions, let us know at any time.

**Genetic Research**

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. To prevent this, the samples will be given a code. Only specified administrators of the repository will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only specified administrators of the repository will have access to your name.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that other people might benefit from this repository in the future through scientific research completed related to diseases and conditions with samples provided by the repository.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be given a choice of a $5.00 gift card or 4 hours of University of Iowa parking passes currently valued at $4.80 as compensation.
WHO IS FUNDING THIS STUDY?

The Roy J. Carver Charitable Trust is funding this research study. This means that the University of Iowa is receiving payments from the Roy J. Carver Charitable Trust to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the Roy J. Carver Charitable Trust for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, your clinical information (dental and medical), saliva, and tissue samples will be stripped of identifiers (such as name, date of birth, address, etc.), labeled with an ID code, and stored in a repository (central storage place), a locked room in the UI College of Dentistry and Dental Clinics. Paper documents will be stored in file cabinets in a locked office, and ID code numbers will be used. Electronic records will be accessed via a password-protected database on password-protected computers. Only research team members will be able to access this information. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about risks associated
with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

**WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?**

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires the University of Iowa College of Dentistry and Dental Clinics to obtain your permission for the research team to access or create “protected health information” about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once the University of Iowa College of Dentistry and Dental Clinics has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under “Confidentiality.”

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Informed Consent Document authorizes the University of Iowa College of Dentistry and Dental Clinics to give us permission to use or create health information about you.

Although you will not be able to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Azeez Butali, University of Iowa, Iowa Institute for, N418 Dental Science Building, 801 Newton Road, Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

**IS BEING IN THIS STUDY VOLUNTARY?**

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won’t be penalized or lose any benefits for which you otherwise qualify.
What if I Decide to Drop out of the Study?
Your participation in this study occurs only one time. However, you have the right to withdraw at any point, which means that your information will be deleted and your samples will be destroyed from the repository. If you decide to leave the study early, we will ask you to please contact Dr. Azeez Butali at (319) 335-8980.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself or experience a research-related injury, please contact Dr. Azeez Butali at (319) 335-8980.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Road, University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office website, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in a special kind of computer listing called a registry. A registry keeps information about you on file so that other researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in different research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry secure on a password protected computer. You may request that your personal information be removed from this file at any time by contacting:

Dr. Azeez Butali
Mailing Address: University of Iowa College of Dentistry
801 Newton Rd, Iowa City, IA 52240
Phone: (319) 335-8980
E-mail: Azeez-butali@uiowa.edu
( )Yes  ( )No  I give you permission to put my name and personal information in a registry so that other researchers can contact me in the future about different research studies.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed):  DO NOT SIGN UNTIL VISIT

Do not sign this form if today's date is on or after EXPIRATION DATE: 08/27/20.

DO NOT SIGN UNTIL VISIT

(Signature of Subject)

DO NOT DATE UNTIL VISIT

(Date)

Parent/Guardian’s Name and Relationship to Subject:

DO NOT SIGN UNTIL VISIT

(Name - printed)

(Relationship to Subject - printed)

Do not sign this form if today’s date is on or after EXPIRATION DATE: 08/27/20.

DO NOT SIGN UNTIL VISIT

(Signature of Parent/Guardian)

DO NOT DATE UNTIL VISIT

(Date)
WITNESS VERIFICATION (if needed for illiterate subjects)

Witness Name and Relationship to Subject:

DO NOT SIGN UNTIL VISIT

(Name - printed)  (Relationship to Subject - printed)

Do not sign this form if today’s date is on or after EXPIRATION DATE: 08/27/20.

DO NOT SIGN UNTIL VISIT

(Signature of Witness)  (Date)

Statement of Person who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

DO NOT SIGN UNTIL VISIT  DO NOT DATE UNTIL VISIT

(Signature of Person who Obtained Consent)  (Date)