

Jacksonville University School of Orthodontics
Data Research Data Registry & Repository

2800 UNIVERSITY BLVD NORTH
JACKSONVILLE, FLORIDA 32211
TEL: (904) 256-7846
FAX: (904) 256-7889

This form alerts you to facts concerning your inclusion in a research data registry and repository ("Registry") related to your orthodontic treatment. You were selected as a possible participant because you have received or will receive orthodontic care at Jacksonville University. We ask that you read this form and ask us any questions you may have before agreeing to be a participant in the Registry. This project is being conducted and funded by the JU Center for Orthodontic Biomaterials Research & Analysis (COBRA)

Project Purpose:

The purpose of the Registry is to create a database of centralized orthodontic clinical information. This data will then be made available to students, faculty and other orthodontic researchers at Jacksonville University for use in research, research studies, educational presentations, and publications.

Project Procedures:

Participants in this project will be asked to do the following:

- 1- Complete the standard registration materials and initial orthodontic examination that all JU patients must complete and undergo before treatment can begin.
- 2- Allow JU to contact you after treatment is completed to determine if you wish to allow JU to obtain additional post treatment data and information.
- 3- Give permission to JU to obtain and transfer clinical information to or from other health care providers as it relates to your orthodontic treatment.

Benefits of Participation:

The direct benefit of participation in this project is that you will have access to an electronic record of your orthodontic health information. This can be easily retrieved for you whenever it becomes necessary.

Additionally, your participation benefits orthodontic research because the use of the clinical information of all the patients registered will enable researchers to learn more about factors involved in the success of certain types of orthodontic treatments and to disseminate this type of information to other dentists who practice orthodontics.

Risks of Participation:

The risk associated with the release of clinical information from your orthodontic health records is that someone may recognize your face. Otherwise, there is no additional risk as no other personal information is disclosed.

Compensation:

You will receive no compensation for your participation in this project.

Participation Related Injury:

Using your orthodontic records in a research database registry cannot result in a physical injury however if you should suffer an injury directly related to obtaining your data, such as tripping over a wire, first aid, emergency, and follow up care as needed will be available in the same manner that it would be for all orthodontic patients. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered an injury related to participation in this project, let JU know in writing right away.

No Confidentiality:

Your clinical information may be reviewed by JU researchers and others involved in the business of orthodontic education. You will be asked to sign a separate release in order for the Registry to use your health/clinical information in any scientific publications or presentations. Because the Registry may include full face pictures and will be used for research, educational lectures and publications, your likeness may be shown to the dental community and may possibly be seen by the general public. In that case, it obviously will not be confidential. No other personal information other than that relating to your orthodontic treatment will ever be revealed.

Voluntary Nature of the Project:

Participation in this project is voluntary. Your decision regarding whether or not to participate will not affect your current or future relations with JU or your orthodontist here. If you decide to participate, you are free to withdraw at any time without affecting those relationships. If you choose to withdraw from this project JU will not share any more of your information with the Registry other than what has been previously stored there.

Contacts and Questions:

If you have any questions regarding this project please contact the Program Director, Dr. Laurance Jerrold, or the person serving in his or her stead, at (904) 256-7847. You may contact JU's Registry in writing or in person at the Jacksonville University School of Orthodontics, 2800 University Blvd. N, Jacksonville, FL 32211.

Personnel from this project may contact you to invite you to participate in other studies. If you do not wish to be contacted, please inform the project staff at (904) 256-7847 and speak with Ms. Sharon Frazier or her stead.

You will be given a copy of this form to keep for your records.

Statement of Consent:

I have read the above information. I have had the opportunity to ask questions and, if I have asked questions, I have received answers. I agree to participate in JU's Research Data Registry & Repository

JACKSONVILLE UNIVERSITY
SCHOOL OF ORTHODONTICS
ORTHODONTIC RESEARCH DATA
REGISTRY AND REPOSITORY

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Authorization to Use & Disclose Orthodontic Information for Research Purposes

1) **Purpose.**

As a patient at JU's orthodontic clinic, I authorize the staff and faculty of Jacksonville University's School of Orthodontics ("JU") to use and disclose my orthodontic information in conjunction with the research project entitled Jacksonville University School of Orthodontics Research Data Registry and Repository. I understand and agree that my information, including models of my teeth, x-rays, photographs, etc may be used for research projects, continuing dental education activities, scientific lectures and/or publications.

2) **Orthodontic Information to be Used or Disclosed.**

My orthodontic information that may be used or disclosed includes: diagnostic and treatment procedures including but not limited to clinical exams, x-rays, facial and dental photographs.

3) **Parties Who May Disclose My Orthodontic Information.**

The researcher and the researcher's staff may disclose my orthodontic information.

4) **Parties Who May Receive or Use My Individual Orthodontic Information.**

The orthodontic information disclosed by JU and myself may be received and used by JU's orthodontic research staff and companies or organizations involved in the business of orthodontic continuing education.

5) **Right to Refuse to Sign This Authorization.**

I do not have to sign this Authorization. If I decide not to sign the Authorization, my information will not be used for any research-related purposes. However, my decision not to sign this authorization will not affect my ability to receive orthodontic treatment or the payment of benefits.

6) **Right to Revoke.**

This authorization does not expire however I can change my mind and withdraw this authorization at any time by sending a written notice to the Jacksonville University School of Orthodontics, 2800 University Blvd. N, Jacksonville, FL 32211. If I withdraw this authorization, it will not affect any actions taken before I did so. The researcher may only use and disclose the information already collected however no further orthodontic data will be collected by or disclosed by JU researchers.

7) **Potential for Re-disclosure.**

Once my orthodontic information is disclosed it may be re-disclosed and cannot be protected by law. For example, your facial photographs (without names), may be seen inadvertently by the general public who may pass by a lecture hall or pick up a professional journal in a doctor's office.

8) **Other laws.**

I understand that there are other laws that may require disclosure of my orthodontic information. Examples include required disclosures for reporting child or spousal abuse and/or neglect, judicial proceedings, State Health Department oversight activities and public health measures.

I am the research participant or his/her personal representative and I have read this information. I have been offered a copy of it after it is signed.