Non-Government Application for Massachusetts All-Payer Claims Data
[Exhibit A]

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. *All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the Organization. This Application and the Data Management Plan will be used by CHIA to determine whether the request meets the criteria for data release, pursuant to* 957 CMR 5.00. *Please complete the Application documents fully and accurately. Prior to receiving CHIA Data, the Organization must execute CHIA's Data Use Agreement. Applicants may wish to review that document prior to submitting this Application.*

Before completing this Application, please review the data request information on CHIA's website:

- Data Availability
- Fee Schedule
- Data Request Process

After reviewing the information on the website and this Application, please contact CHIA at apcd.data@state.ma.us if you have additional questions about how to complete this form.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the CHIA website in Word and in PDF format or on IRBNet in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website and IRBNet. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

II. FEE INFORMATION

1. Consult the most current Fee Schedule for All-Payer Claims Database data.

2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact apcd.data@state.ma.us.

3. If you believe that you qualify for a fee waiver, complete and submit the Fee Remittance Form and attach it and all required supporting documentation with your application. Refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.

4. Applications will not be reviewed until the application fee is received.

5. Data for approved Applications will not be released until the payment for the Data is received.

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Root Canal Therapy in Children: Analysis of Disparities and Value
IRBNet Number:	1491238-1
Organization Requesting Data (Recipient):	New York University College of Dentistry
Organization Website:	https://dental.nyu.edu
Authorized Signatory for Organization:	Nancy Daneau
Title:	Assistant Vice Provost for Research
E-Mail Address:	Osp.agency@nyu.edu
Address, City/Town, State, Zip Code:	665 Broadway, Suite 801, New York, NY 10012
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	Lorel E. Burns, DDS, MS
Title:	Assistant Professor, Department of Endodontics
E-Mail Address:	Leb409@nyu.edu
Telephone Number:	212-998-9332
Address, City/Town, State, Zip Code:	345 E. 24th Street, 4W, New York, NY 10010
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Lorel E. Burns, DDS, MS
Title:	Assistant Professor, Department of Endodontics
E-Mail Address:	Leb409@nyu.edu
Telephone Number:	212-998-9332
Names of Co-Investigators:	Heather Gold, PhD; Keith Goldfeld, DrPh
E-Mail Addresses of Co-Investigators:	Heather.Gold@nyulangone.org; Keith.Goldfeld@nyulangone.org

IV. PROJECT INFORMATION

1. What will be the use of the CHIA Data requested? [Check all that apply]

☐ Epidemiological	☐ Health planning/resource allocation	☐ Cost trends
☒ Longitudinal Research	☐ Quality of care assessment	☐ Rate setting
☐ Reference tool	☒ Research studies	☐ Severity index tool
☐ Surveillance	☐ Student research	☐ Utilization review of resources
☐ Inclusion in a product	☐ Other (describe in box below)	

2. Provide an abstract or brief summary of the specific purpose and objectives of your Project. This description should include the research questions and/or hypotheses the project will attempt to address, or describe the intended product or report that will be derived from the requested data and how this product will be used. Include a brief summary of the pertinent literature with citations, if applicable.

This proposal will use robust, proven analytic methods to estimate prevalence and outcomes of root canal therapy of permanent teeth in a pediatric population in the United States.

Aim 1: Evaluate the prevalence and outcomes of primary root canal therapy of permanent teeth in a pediatric population and determine factors associated with treatment survival using administrative claims data. Clinical characteristics to be studied include: patient sex, age, race/ethnicity, geographic location, insurance type (public vs. private payer), tooth type, practitioner type, time to / type of coronal restoration.

H1a: Root canal therapy in permanent teeth of children will vary in survival rate and subsequent treatment compared with studies of adults.
H1b: Clinical characteristics will be significantly associated with survival of root canal therapy.
H1c: Disparities in time to coronal restoration, type of coronal restoration, practitioner type, and survival rates will vary by payer type and area-based poverty/education levels.

Aim 2: **Explore dental / emergency room (ER) utilization rates and spending associated with teeth that undergo root canal therapy**.
H3: Clinical characteristics and frequency of adverse events will be associated with downstream utilization rates and dental spending.

3. Has an Institutional Review Board (IRB) reviewed your Project?

☒ Yes [*If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.*]
☐ No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology**: Applicants must provide either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

V. PUBLIC INTEREST

1. Briefly explain why completing your Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. *Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.*

Knowledge of treatment prognosis is important for appropriate case selection and treatment planning. The most recent information available on the frequency of endodontic procedures is from the American Dental Association Survey of Dental Services Rendered, conducted in 2005-2006 and published in 2007. In the endodontic literature, population-based outcome studies of root canal therapy in the US utilize data from a single, private dental insurer and do not specify patient age. However, the findings from the adult-focused literature may not be applicable to the pediatric population due to both physical and behavioral factors, but also because other types of endodontic treatment may serve as alternatives in these cases. The proposed study will fill current gaps in knowledge.

This research has the potential to immediately translate into both clinical practice and dental policy by providing an in-depth understanding of endodontic treatment in a pediatric population. This is essential to developing best care practices and quality measures.

VI. DATA REQUESTED

The Massachusetts All-Payer Claims Database is comprised of medical, pharmacy, and dental claims and information from the member eligibility, provider, and product files that are collected from health insurance payers licensed to operate in the Commonwealth of Massachusetts. This information encompasses public and private payers as well as data from insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. Data requests will be fulfilled using the most current Release Version. For more information about the most current APCD Release Version, including available years of data and a full list of elements in the release please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require future years of data that will become available in a subsequent release. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial Release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

1. List years of data requested (only list years available in the current Release Version): 2013-2017 , release 7.0

2. Please indicate below whether this is a one-time request, or if the described Project will require a subscription.

☒ One-Time Request **OR** ☐ Subscription

3. Specify below the data files requested for this Project, and provide your justification for requesting *each* file.

☒ **Medical Claims**
Describe how your research objectives require Medical Claims data: Medical claims data will be used explore emergency room utilization rates and spending associated with children that undergo root canal therapy in order to assess tradeoffs between the number/ type of adverse events and spending.
☐ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data: N/A
☒ **Dental Claims**
Describe how your research objectives require Dental Claims data:

Dental claims data will be used to evaluate the prevelance and outcomes of root canaly therapy of permanent teeth in a pediatric population and determine factors associated with primary root canal therapy survival.

☒ **Member Eligibility**

Describe how your research objectives require Member Eligibility data:

Data will be analyzed to assess disparities in outcomes and treatment process by payer type.

☒ **Provider**

Describe how your research objectives require Provider data:

An evaluation of how independent variables, including provider type (endodontist vs. other types of dentists) impact both the primary outcome of procedure survival and the secondary outcome of time to final restoration after root canal therapy will be analyzed.

☐ **Product**

Describe how your research objectives require Product data:

N/A

VII. DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of Data to the minimum amount of data needed to accomplish a specific Project objective.

All-Payer Claims Database data is released in Limited Data Sets (LDS). All applicants receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the core elements and additional elements), please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS, provide your justification for requesting each enhancement.

Geographic Subdivisions

The geographic subdivisions listed below are available for Massachusetts residents and providers only. Select *one* of the following options.

☐ 3-Digit Zip Code (standard)	☒ 5-Digit Zip Code***

***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: Our research methodology proposes that the claims data be merged with US Census data and HRSA Area Health Resource files. Census data will be used to ascertain area-based socioeconomic measures (SES) in patient zip-code area (percentage of residents living below poverty, without a high school education, rural status) using Census year closest to the initial treatment date. HRSA's Area Health Resource File will be used to determine health professional shortage areas by county, representing limited access to dental care.

Date Resolution

Select *one* option from the following options.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: One of the outcomes in this study is time to permanent restoration after the completion of root canal therapy. This needs to be trached at the time interval of days.		

National Provider Identifier (NPI)

Select *one* of the following options.

☒ Encrypted National Provider Identifier(s) (standard)	☐ Decrypted National Provider Identifier(s)***
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: N/A	

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☒ Yes
☐ No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

This project is not interested in the use of individually identifiable data of Medicaid recipients for uses that are directly connected to the administration of the Medicaid program. This research does, however, propose the use of de- identified Medicaid data to assess for disparities in treatment outcomes and processes by payer type (public vs. private payer). This type of analysis may be used by the Executive Office of Health and Human Services in connection with the administering of the MassHealth program in their efforts to improve the dental health of Massachusetts children. Specifically, this research use of MassHealth data my be helpful in determining access to dental care amongst its beneficiaries. The results of this proposed project may also highlight points of strength and areas for potential improvement in treatment process of its beneficiaries and cost-effectiveness of its program.

IX. DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?

☒ Yes

☐ No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]

☐ Individual Patient Level Data (e.g. disease registries, death data)

☐ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)

☐ Individual Facility Level Data (e.g., American Hospital Association data)

☒ Aggregate Data (e.g., Census data)

☒ Other (please describe): Health Resources and Service Area (HRSA) Health Resource file

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

The CHIA data will be merged with 2010 US Census data and HRSA's Area Health Resource File by year. Census data will be used to ascertain area-based socioeconomic measures (SES) in patient zip-code area (percentage of residents living below poverty, without a high school education, rural status) using Census year closest to the initial treatment date. HRSA's Area Health Resource File will be used to determine health professional dental health professions shortage areas by county, representing limited access to dental care.

The linkage of data will enhance previously used methods by linking other data sources to the dental claims data in order to analyze how socioeconomic factors and system factors are associated with endodontic outcomes.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

We will use deterministic linking by Zip Code Tabulation Area for Census data and FIPS state/county code for HRSA/HPSA data.

5. If yes, attach or provide below a complete listing of the variables from all sources to be included in the final linked analytic file.

Census (merge by ZCTA) :
1. total population
2. number of persons living below the poverty level
3. number of persons without high school education
4. number of persons living in rural area
We will create new variables of the proportions of 2-4 divided by total population.

HRSA Area Health Resource File (merge by state/county FIPS code):
1. Dental health professions shortage area

6. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

These are area-level variables (county, zip code area) and not at the patient level; therefore we expect we will not add any risk of identification of individual patients.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications ***will not disclose a cell less than 11***, and percentages or other mathematical formulas that result in the display of a cell less than 11.

Sharing of data generated by this project is an essential part of our proposed activities and will be carried out in several different ways.

1) New secondary data analyses will be published independently from the model results. Due to data use agreements and Federal regulations governing privacy and compliance, however, we are unable to share the data themselves

2) We aim to make our results available to the scientific community. Therefore, the findings from this study will be published and presented at national meetings, the most traditional approaches to sharing study results. The results will be presented at the

major scientific meetings related to dentistry and health services research including the American Association of Dental Research, AcademyHealth, and the American Association of Endodontists annual meetings.

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

N/A

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

City/ town level will be the lowest level of geographical level of analysis of data expected for publication/ presentation. Maps are not planned for presentation. There is no intention of identifying individuals and information will be presented in aggregate as a weay to ensure that individual cannot be identified.

4. Will you be using CHIA Data for consulting purposes?

☐ Yes
☒ No

5. Will you be selling standard report products using CHIA Data?

☐ Yes
☒ No

6. Will you be selling a software product using CHIA Data?

☐ Yes
☒ No

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment tool, reference tool, etc.)

☐ Yes
☒ No

8. Will you be reselling CHIA Data in any format not noted above?

☐ Yes
☒ No

If yes, in what format will you be reselling CHIA Data?

N/A

9. If you have answered "yes" to questions 5, 6, 7 or 8, please describe the types of products, software, services, or tools.

N/A

10. If you have answered "yes" to questions 5, 6, 7 or 8, what is the fee you will charge for such products, software, services or tools?

N/A

XII. APPLICANT QUALIFICATIONS

1. Describe your previous experience using claims data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

Lorel E. Burns DDS,MS: Principal Investigator, Assistant Professor, New York University College of Dentistry.

- Dr. Burns is funded by an NIH/NIDCR Career Development Award (1K01DE028591-01A1) and planned training and mentorship for the use of Claims data.

Heather T. Gold, PhD: Co-Investigator, Professor, NYU Langone Heath, Department of Population Health

- Dr. Gold is serving as Dr. Burns' mentor on this project. Dr, Gold has extensive experience with claims data
- Dr. Gold's work uses health services research to determine how socioeconomic, racial/ethnic, geographic, and clinical variations in health care affect health and economic outcomes, especially in cancer, orthopedics, and patients with multiple comorbid conditions. With a unique, multi-methods and multidisciplinary approach, she aims to shed new light on compelling questions and translate my research into policies that encourage appropriate use of healthcare services. She applies complex quantitative methods for analyzing large, population-based data (e.g., SEER-Medicare, Medicare, state all-payer, and healthcare system data) and mathematical modeling using decision and cost-effectiveness analysis. She also uses qualitative methods to explore clinician and patient decision-making experiences. She is an expert in costing out health interventions for economic analysis and am the health economics co-investigator on several funded projects that include cost-effectiveness and claims data analyses. The findings of my research inform optimal care coordination and evidence-based interventions to reduce avoidable morbidity and mortality.

Keith S. Goldfeld, DrPH: Co-investigator, Assistant Professor, NYU Langone Heath,
Division of Biostatistics, Department of Population Health

- Dr. Goldfeld serves as an advisor on Dr. Burns' project.
- Dr. Goldfeld has a broad background in statistical analysis, with specific training and expertise in biostatistical methods and applications. His research interests include health services research, cluster randomized trials, causal inference, observational data analysis, and cost-effectiveness analysis. In addition, he has collaborated with investigators to analyze outcomes for patients with advanced dementia, COPD, hypertension, addiction, and palliative care.

2. **Resumes/CVs**: When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Agency must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.]*

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	**N/A**
Company Website	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

N/A

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

N/A

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☒ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	N/A
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

N/A

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

N/A

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes

☒ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

IVX. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Applicants approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (4) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	Nancy Daneau
Printed Name:	Nancy Daneau
Title:	Assistant Vice Provost for Research

Attachments

A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:

☒ 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)

☒ 2. Data Management Plan; including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database

☒ 3. CVs of Investigators (upload to IRBnet)

APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.

[INSERT IRB approval letter and protocol, or research methodology]

- IRB protocol and IRB approval letter have been submitted through IRBnet

NYU School of Medicine

Office of Science and Research
Institutional Review Board
1 Park Avenue | 6th Floor | New York, NY 10016

Approval of Submission

September 23, 2019

On 9/23/2019 the IRB reviewed and approved the following submission:

principal investigator	Lorel Burns
study number	i19-01436
study title	Root Canal Therapy in Children: An Analysis of Disparities and Value
performance period	9/23/2019 - 9/22/2020
location(s)	College of Dentistry (NYU School or College)
sponsor(s)	Name: NIH-NIDCR
review type	Initial Study, Expedited Category 5
board name	All boards
materials approved for use	• Protocol, Category: IRB Protocol; • Waiver of authorization and consent, Category: Consent Form;

This study involves a vulnerable population: children. In accordance with 45 CFR 46.401 and NYU Policy the IRB has determined that this research involves minimal risk (45 CFR 46. 404). A request for waiver of Authorization to use identifiable health information for research has been approved in accordance with 45 CFR.164.512(i). A waiver of Informed Consent has been granted in accordance with 45 CFR 46.116 (f).

The current IRB Status of your submission is: Approved. This submission was reviewed by the NYU School of Medicine's Institutional Review Board (IRB). During the review of your study, the IRB specifically considered:

1. the risks and anticipated benefits (if any) to your subjects
2. the selection of subjects
3. the procedures for securing and documenting informed consent
4. the safety of your subjects
5. the privacy of your subjects and confidentiality of the data

Your study cannot commence until all ancillary review decisions are complete. To determine the state of all ancillary reviews, go the MyStudies page of this study in Research Navigator. Ancillary review statuses are located on the top/right area of your study's main screen.

Note: Ensure that approval has been issued in MyAgreements/CRMS and the Clinical Research Support Unit ("CRSU") before you proceed with any aspect of this study, including the enrollment of human subjects.

Review Notes

For NIH grant funded research approved before the revised Common Rule: the IRB has found the IRB approved protocol referenced above to be consistent with the NIH grant application.

Sincerely,

Helen Panageas 9/23/2019

RE: Study# i19-01436
Helen Panageas
Director, NYU SoM Institutional Review Board
Federalwide Assurance: FWA00004952

NYU School of Medicine's IRB operates in accordance with Good Clinical Practices (GCP) and applicable laws and regulations. Federal rules allow IRBs to document their determination/authorization process in their policy manual. Determination letters generated by NYU SoM's IRB administration system are not physically signed as per policy. All approved study materials are clearly identified and locked in each study submission record within the IRB's administration system.

NYU School of Medicine IRB Policy

- *All current IRB policy documents can be found on our website*
- *You must submit all modifications to this study (e.g., protocol updates, modified recruitment materials, consent forms, etc.) using Research Navigator to communicate with the IRB ("eSubmission") for review and approval prior to initiation of those change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.*
- *All adverse and/or unanticipated event(s) that occur while conducting this study must immediately be reported to the IRB via eSubmission.*
- *You may only use IRB-approved copies of your consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your study. Never use expired consent forms.*
- *If modifications are made to the study or adverse events occur while conducting study, the PI must inform all research staff listed on this study.*
- *IRB's approval is valid as per the period indicated above. A reminder to submit a continuation (should one be required) will be e-mailed to the PI, PI Proxy and Primary Contact 90, 60 and 30 days prior to this study's expiration date if one is indicated. After expiration, a daily reminder will be sent for 30 days followed by a weekly reminder until the study receives re-approval or a study closure.*
- *Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative for each site where your study will take place. Key contacts are:*
  - Bellevue Hospital (BHC): if you are conducting all or part of your study at BHC, you must contact them to obtain additional approvals. BHC will be notified if any of their sites are selected as a location where your study takes place, but your team is obligated to contact them at BellevueResearch@bellevue.nychhc.org to find out what approvals are required before conducting any research at a BHC location.
  - *CTSI - Clinical and Translational Science Institute, NYU School of Medicine [formerly General Clinical Research Center (GCRC)]: email ctsi@nyulangone.org*
  - *NYU Langone Health Centers (Tisch Hospital/Rusk Institute/Co-op Care/HJD/Perlmutter Cancer Center) site approval is handled for you automatically (as needed) by the CRSU*
- *The IRB may suspend or terminate studies that are not in compliance with NYU Langone Health/School of Medicine Policies & Procedures and the requirements of the Institution's Federal Wide Assurance with the federal government.*
- *Direct IRB questions and comments to 212-263-4110 or IRB-INFO@nyulangone.org*

Let Us Know How We're Doing

Click on the title above to send us feedback via a short, anonymous survey. Providing exceptional customer service is a top priority of the IRB and your responses will help us understand how we can continue to improve our service to the research community.

NYU School of Medicine
NYU LANGONE MEDICAL CENTER

Institutional Review Board
Human Research Protection Program
1 Park Avenue | 6th Floor | New York, NY 10016
http: – – irb.med.nyu.edu

IRB Board Rosters

Effective **2019-08-06** FWA#00004952

Quorum is simple majority only = greater than half

Board A (Effective 2019-08-06)

Members; Quorum of 7; 8 for prisoner-related studies

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
More, Frederick (Chair)	DDS	S	Dentistry – Pediatrics	Y	Hazen, Katz, Nishawala, Novik, Wissner-Greene
Donnino, Robert (Vice Chair)	MD	S	Medicine – Cardiology	Y	Vice Chair Alternates: Hazen, Nishawala, GreeneMember Alternates: Culliford, Katz
Basu Roy, Upal	PhD, MPH	S	Community Representative	N	Abramovitz, Raskin, Wu
Bliss, Samuel	PharmD	S	Pharmacy	Y	Ballani, Dubrobskaya, Faiena, Wong
Diefenbach, Catherine	MD	S	Oncology	Y	Esteva, Kwa, Moskovitz, Novik, Rapp, Ryan, Saint Fleur, Schiff, Wu
Gallagher, Richard	PhD	S	Child & Adolescent Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, McGregor, Nishawala, Rotrosen
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez, Johnson
Kadidal, Shane *	JD	NS	Law – Prisoner Advocate	N	
Lamont, Justin	MD	S	Orthopedic Surgery	Y	Kirsch, Leucht, Rapp
Panageas, Helen	BA	NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Vieira, Wallach
Ross-Rizzo, John	MD	S	Neurology	Y	Barr, Berk, Chervinsky, Lewis
Ross, Stephen	MD	S	Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, McGregor, Nishawala, Rotrosen
Storey, Elizabeth	PhD	S	Radiology	Y	Bencardino, Fieremans, Gonen
Wang, Jing	MD	S	Anesthesiology	Y	Kim

Counts toward quorum only when reviewing studies subject to Subpart C

Board B (Effective 2019-08-06)

Members; Quorum of 9, 9 for prisoner-related studies

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
Katz, Stuart (Chairman)	MD PhD	S	Cardiology	Y	Donnino, Hazen, More, Nishawala, Novik, Wissner-Greene
Hazen, Alexes (Vice Chair)	MD	S	Surgery – Plastic	Y	Vice Chair Alternates: Donnino, More, Nishawala, Novik, Wissner-Greene Member Alternates: DeLacure
Bartlett, Rachel	PhD	S	Radiology	Y	Bencardino, Fieremans, Gonen, Storey
Berk, Thomas	MD	S	Neurology	Y	Barr, Lewis, Ross-Rizzo
Brar, Preneet	MD	S	Pediatric Endocrinology	Y	Ramirez, Tunik, Wissner-Greene
Culliford, Alfred	MD	S	Surgery – Cardiothoracic	Y	Donnino, Lamont, Rapp
Dubrovskaya, Yanina	PharmD	S	Pharmacy	Y	Ballani, Bliss, Faiena, Wong
Esteva, Francisco	MD	S	Oncology	Y	Diefenbach, Moskovits, Novik, Rapp, Ryan, Saint Fleur, Schiff, Wu
Frankle, William Gordon	MD	S	Psychiatry	Y	Barr, Bogenschutz, Gallagher, McGregor, Nishawala, Ross, Rotrosen
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez Johnson
Kadidal, Shane *	JD	NS	Law-Prisoner Advocate	N	
Kirsch, Thorsten	PhD	S	Orthopedic Surgery	Y	Lamont, Leucht, Rapp
Kwa, Maryann	MD	S	Oncology	Y	Diefenbach, Moskovits, Novik, Rapp, Ryan, Saint Fleur, Schiff, Wu
McGowan, Richard	MLS	NS	Public Services	Y	Vieira
Nolan, Anna	MD	S	Pulmonary	Y	
Panageas, Helen	BA	NS	IRB Administration	Y	Dvorkin, Liu, Vieira, Wallach
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz, Basu Roy, Wu

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Board C (Effective 2019-08-06)

Members; Quorum of 6; 7 for prisoner-related studies

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
Novik, Yelena (Chair)	MD	S	Oncology	Y	Donnino, Hazen, Katz, More, Nishawala, Wissner-Greene
Nishawala, Melissa (Vice Chair)	MD	S	Child & Adolescent Psychiatry	Y	Vice Chair Alternates: Donnino, Hazen, Katz, More, Wissner-Greene Member Alternates: Barr, Bogenschutz, Chervinsky, Frankle, Gallagher, McGregor, Ross, Rotrosen
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez, Johnson
Chervinsky, Alexander B	PhD	S	Neuropsychology	Y	Barr, Bogenschutz, Gallagher, Lewis, McGregor, Nishawala, Ross, Rotrosen
Kadidal, Shane *	JD	NS	Law – Prisoner Advocate	N	
Kim, Sunmi	MD	S	Anesthesiology	Y	Wang
Panageas, Helen	BA	NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Wallach
Schiff, Peter	MD	S	Radiation Oncology	Y	Diefenbach, Esteva, Kwa, Moskovits, Rya, Saint Fleur
Vieira, Dorice	MA	NS	Public Services	Y	McGowan
Wong, Doris	PharmD	S	Pharmacy	Y	Ballani, Bliss, Dubrovskaya, Faiena
Wu, Jennifer	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Moskovits, Ryan, Saint Fleur
Wu, Lillian	BA, MA	NS	Community Representative	N	Abramovitz, Basu Roy, Raskin

**Counts toward quorum only when reviewing studies subject to Subpart C*

Board D (Effective 2019-08-06)

Members; Quorum of 9; 9 for prisoner-related studies

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
More, Frederick (Chair)	DDS	S	Dentistry – Pediatrics	Y	Donnino, Hazen, Katz, Nishawala, Novik, Wissner-Greene
Wissner-Greene, Loren (Vice Chair)	MD, MA	S	Medicine – Endocrinology – Ob-Gyn	Y	Vice Chair Alternates: Donnino, Hazen, Katz, More, Nishawala, Novik, Member Alternate: Brar
Abramovitz, Rachel	LL.M., LL.B.	NS	Community Representative	N	Basu Roy, Raskin, Wu
Ballani, Kanika	PharmD	S	Pharmacy	Y	Bliss, Dubrovskaya, Faiena, Wong
Barr, William	PhD	S	Neuropsychology	Y	Berk, Chervinsky, Frankle, Gallagher, Lewis, McGregor, Nishawala, Ross, Ross-Rizzo, Rotrosen,
Bogenschutz, Michael	MD	S	Psychiatry	Y	Chervinsky, Frankle, Gallagher, McGregor, Nishawala, Ross, Rotrosen
Dedania, Vaidehi	MD	S	Ophthalmology	Y	
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez, Johnson
Gonen, Oded	PhD	S	Radiology	Y	Bartlett, Bencardino, Fieremans, Storey
Kadidal, Shane *	JD	NS	Legal – Prisoner Advocate	N	
Leucht, Philipp	MD, PhD	S	Orthopaedic Trauma	Y	Kirsch, Lamont, Rapp
Mehta-Lee, Shilpi	MD	S	Ob-Gyn	Y	
Panageas, Helen		NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Vieira, Wallach
Ramirez, Michelle	MD	S	Pediatric Critical Care	Y	Brar, McGregpr, Oshva, Tunik
Ryan, Theresa	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Novik, Rapp, Schiff, Wu
Saint Fleur, Shella	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Novik, Rapp, Schiff, Wu

**Counts toward quorum only when reviewing studies subject to Subpart C*

Board E (Effective 2019-08-06)

Members; Quorum of 4; 4 for prisoner-related studies

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
More, Frederick (Chair)	DDS	S	Dentistry	Y	Donnino, Hazen, Katz, Nishawala, Novik, Wissner-Greene
Katz, Stuart (Vice-Chair)	MD	S	Cardiology	Y	Vice Chair Alternates: Donnino, Hazen, More, Nishawala, Novik, Wissner-Greene Member Alternates: Culliford, Donnino
Johnson, Nadia	MS	S	IRB Administration	Y	Berkovitz, Godina, Jeschke-Lopez
Wu, Jennifer	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Moskovits, Novik, Rapp, Ryan, Saint Fleur, Schiff
Kadidal, Shane *	JD	NS	Law-Prisoner Advocate	N	
Panageas, Helen		NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Vieira, Wallach
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz, Basu Roy, Wu

**Counts toward quorum only when reviewing studies subject to Subpart C*

Alternates

Alternate	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate For
Abramovitz, Rachel	LL.M., LL.B.	NS	Community Representative	N	Basu Roy, Raskin, Wu
Ballani, Kanika	PharmD	S	Pharmacy	Y	Bliss, Dubrovskaya, Wong
Barr, William	PhD	S	Neuropsychology	Y	Berk, Chevinsky, Frankle, Gallagher, Nishawala, Ross, Ross-Rizzo
Bartlett, Rachel	PhD	S	Radiology	Y	Gonen, Storey
Basu Roy, Upal	PhD, MPH	S	Community Representative	Y	Abramovitz, Raskin, Wu
Bencardino, Jenny	MD	S	Radiology	Y	Bartlett, Gonen, Schiff
Berk, Thomas	MD	S	Neurology	Y	Barr, Ross-Rizzo
Berkovitz, David	MD	S	IRB Administration	Y	Godina
Bliss, Samuel	PharmD	S	Pharmacy	Y	Ballani, Dubrovskaya, Wong
Bogenschutz, Michael	MD	S	Psychiatry	Y	Barr, Chervinsky, Frankle, Gallagher, Nishawala, Ross
Brar, Preneet	MD	S	Pediatric Endocrinology	Y	Ramirez, Wissner-Greene
Chervinsky, Alexander	PhD	S	Neuropsychology	Y	Barr, Bogenschutz, Gallagher, Nishawala, Ross, Ross-Rizzo
Culliford, Alfred	MD	S	Surgery – Cardiothoracic	Y	Donnino, Katz
DeLacure, Mark D	MD	S	Otolaryngology & Plastic Surgery	Y	Hazen
Diefenbach, Catherine	MD	S	Oncology	Y	Esteva, Kwa, Ryan, Saint Fleur, Schiff, Wu
Donnino, Robert	MD	S	Medicine – Cardiology	Y	Culliford Hazen, Katz, More, Nishawala, Novik, Wissner-Greene
Dubrovskaya, Yanina	PharmD	S	Pharmacy	Y	Ballani, Bliss, Wong
Dvorkin, Ella		NS	IRB Administration	Y	Panageas
Esteva, Francisco	MD	S	Oncology	Y	Diefenbach, Kwa, Ryan, Saint Fleur, Schiff, Wu
Faiena, Mark	PharmD	S	Pharmacy	Y	Ballani, Bliss, Dubrovskaya, Wong
Fieremans, Els	PhD		Radiology	Y	Bartlett, Gonen, Storey
Frankle, William Gordon	MD	S	Psychiatry	Y	Barr, Bogenschutz, Gallagher, Nishawala, Ross
Gallagher, Richard	PhD	S	Child & Adolescent Psychiatry	Y	Chervinsky, Frankle, Nishawala, Ross
Gonen, Oded	PhD	S	Radiology	Y	Bartlett, Storey
Hazen, Alexes	MD	S	Plastic Surgery	Y	Katz, More, Nishawala, Novik, Wissner-Greene
Jeschke-Lopez, Ikoa	MD	S	IRB Administration	Y	Godina
Johnson, Nadia	MS	S	IRB Administration	Y	Godina
Katz, Stuart	MD	S	Cardiology	Y	Donnino, Hazen, More, Nishawala, Novik, Wissner-Greene
Kim, Sunmi	MD	S	Anesthesiology	Y	Wang
Kirsch, Thorsten	MD	S	Orthopedic Surgery	Y	Lamont, Leucht, Rapp
Kwa, Maryann	MD	S	Oncology	Y	Diefenbach, Novik, Ryan, Saint Fleur, Schiff, Wu

Lamont, Justin	MD	S	Orthopedic Surgery	Y	Culliford, Hazen, Kirsch, Leucht, Rapp
Leucht, Philipp	MD, PhD	S	Orthopaedic Trauma	Y	Kirsch, Lamont, Schiff
Liu, Jasmine	BS	NS	IRB Administration	Y	Panageas
Lewis, Ariane	MD	S	Neurocritical Care	Y	Barr, Berk, Ross-Rizzo
McGowan, Richard	MLS	NS	Public Services	Y	Panageas, Vieira
McGregor, Kyle	PhD	S	Child & Adolescent Psychiatry	Y	Barr, Bogenschutz, Chervinsky,Frankle, Gallagher, Nishawala, Ross
More, Frederick	DDS	S	Dentistry – Pediatric	Y	Hazen, Katz, Nishawala, Novik, Wissner-Greene
Moskovits, Tibor	MD	S	Hematology – Oncology	Y	Diefenbach, Esteva, Kwa, Ryan, Saint Fleur, Schiff, Wu
Nishawala, Melissa	MD	S	Child & Adolescent Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, Hazen, Katz, More, Novik, Ross, Wissner-Greene
Nolan, Anna	MD	S	Pulmonary	Y	
Novik, Yelena	MD	S	Oncology	Y	Diefenbach, Esteva, Katz, Kwa, Hazen, More, Nishawala, Ryan, Saint Fleur, Wissner-Greene, Wu
Oshva, Lillian	MD	S	Emergency Medicine	Y	Ramirez
Ramirez, Michelle	MD	S	Pediatric Critical Care	Y	Brar
Rapp, Timothy	MD	S	Orthopedic Surgery – Oncology	Y	Culliford, Diefenbach,Esteva, Kirsch, Kwa, Lamont, Leucht, Ryan, Saint Fleur, Schiff, Wu
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz, Basu Roy, Wu
Ross, Stephen	MD	S	Addiction Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, Nishawala
Ross-Rizzo, John	MD	S	Neurology	Y	Barr, Chervinsky,
Rotrosen, John	MD	S	Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, Gallagher, Nishawala, Ross
Ryan, Theresa	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Novik, Saint Fleur, Schiff, Wu
Saint Fleur, Shella	MD	S	Hematology - Oncology	Y	Diefenbach, Esteva, Kwa, Novik, Ryan, Schiff, Wu
Schiff, Peter	MD	S	Radiation – Oncology	Y	Diefenbach, Esteva, Kwa, Ryan, Saint Fleur, Wu
Storey, Elizabeth	PhD	S	Radiation	Y	Bartlett, Gonen
Tunik, Michael	MD	S	Pediatric EM	Y	Brar, More, Ramirez
Vieira, Dorice	MA	NS	Public Services	Y	McGowan, Panageas
Wallach, David	BA , MPH	NS	IRB Administration	Y	Panageas
Wang, Jing	MD	S	Anesthesiology	Y	Kim
Wissner-Greene, Loren	MD, MA	S	Medicine – Endocrinology – Ob-Gyn	Y	Brar, Hazen, Katz, More, Nishawala, Novik,
Wong, Doris	PharmD	S	Pharmacy	Y	Ballani, Bliss, Dubrovskaya,
Wu, Jennifer	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Ryan, Saint Fleur
Wu, Lillian	BA, MA	NS	Community Representative	N	Abramovitz, Basu Roy, Raskin

Title: Root Canal Therapy in Children: An Analysis of Disparities and Value

NIDCR Grant Number: 1K01DE028591-01A1

Principal Investigator: Lorel E. Burns, DDS, MS

NIDCR Program Official: Lynn Mertens King, PhD

Draft or Version Number: 2.0

19 September 2019

STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIDCR Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects protection training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator or Clinical Site Investigator:

Signed: Lorel E. Burns, DDS Date: 09/19/2019

Name: Lorel E. Burns, DDS, MS

Title: Assistant Professor, Department of Endodontics, NYU College of Dentistry

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CRF	Case Report Form
CSOC	Clinical Study Oversight Committee
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data and Safety Monitoring Board
FFR	Federal Financial Report
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
ISM	Independent Safety Monitor
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
US	United States

PROTOCOL SUMMARY

Title:	Root Canal Therapy in Children: An Analysis of Disparities and Value
Précis:	The study design is a retrospective, longitudinal, population-based cohort study. Administrative data claims will be used to analyze treatment outcomes and processes of care.
Objectives:	Aim 1: Evaluate the prevalence and outcomes of primary root canal therapy of permanent teeth in a pediatric population and determine factors associated with treatment survival using administrative claims data. Aim 2: Explore dental / emergency room (ER) utilization rates and spending associated with teeth that undergo root canal therapy.
Population:	Population will include males and females aged 6-18 We will include children ages 6-18 who've had at least one primary root canal therapy on a permanent tooth. The population will include all children with dental coverage in Massachusetts and children with public payer dental insurance in New York State.
Number of Sites:	All data analysis will occur in one site, New York University
Study Duration:	Study duration is anticipated to be from October 2019 – March 2020
Subject Participation Duration:	Not applicable, this is secondary data analysis
Estimated Time to Complete Enrollment:	Not applicable, this is secondary data analysis

Schematic of Study Design:

Step 1 **Acquire/ Clean/ Merge Administrative Claims Data**
(Months 1-12)

Step 2 **Data Analysis**
(Months 7-18)

Step 3 **Cost Analysis**
(Months 19-24)

Final Assessments

1 KEY ROLES AND CONTACT INFORMATION

Principal Investigator:	Lorel E. Burns, DDS, MS Assistant Professor, Department of Endodontics, NYU College of Dentistry New York University College of Dentistry 345 E. 24th Street, 4W New York, NY 10010 Phone: 212-998-9332 Email: leb409@nyu.edu
NIDCR Program Official:	Lynn Mertens King, PhD
Clinical Site Investigators:	N/A
Institutions:	New York University College of Dentistry 345 E. 24th Street, New York, NY 10010

Other Key Personnel:	• Mentor: Heather T. Gold, PhD, Professor, Department of Population Health, NYU Langone Health
	• Data Analysis Assistants:
	  ○ Claudia Solis-Roman
	  ○ Kelly Terlizzi
	• Statistician: Keith Goldfeld, DrPH, Assistant Professor, Division of Biostatistics, Department of Population Health, NYU Langone Health

2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Dental coverage of children and dental care utilization by children in the United States are at their highest-ever levels since tracking began in 1999. As resources increasingly go towards coverage of dental services, it is important to rigorously assess dental treatment quality and outcomes. Although the dental profession has greatly improved its efforts to identify and develop evidence-based performance measures, there is currently not a single quality measure for endodontics, the dental specialty committed to preserving teeth.

The most common endodontic procedure is root canal therapy, performed over 15 million times annually in the United States as management for tooth pain and infection. To date, the literature on root canal therapy outcomes in the United States is based primarily on adult populations, even as children also undergo root canal therapy. Treatment of the permanent dentition in children differs from that of adults due to anatomical differences and behavioral factors. Clinicians may encounter difficulties making informed treatment planning decisions and evaluating quality of endodontic care in the pediatric population due to a lack of information on the prevalence and outcomes of root canal therapy in children. The most recent information available on endodontic procedure frequency is from the American Dental Association Survey of Dental Services Rendered, conducted in 2005-2006 and published in 2007. The lack of information about endodontic procedure utilization, the absence of linkages to patient demographics, and the dearth of robust outcomes analyses for this treatment in a pediatric population highlight the need for updated, rigorous research in this area.

2.2 Rationale

The objective of the proposed research plan is to fill gaps in knowledge concerning endodontic care and outcomes for children in the Unites States. multiple facets of the clinical management of dental pain and infection in children can be evaluated, specifically a quantitative assessment of treatment and outcomes in a large, population-based sample.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

Though we expect the level of risk due to this intervention to be minimal, potential risks to the patient may include the following:

Data Breach: A data breach leading to loss of confidentiality is the greatest potential risk to study subjects. Efforts will be made to ensure that the data are both protected and de-identified.

Data agreements between the New York University Health Evaluation and Analytics Lab (HEAL) and Center for Health Information Analysis (CHIA), the providers of the described datasets, ensure that direct identifiers will be removed from the datasets prior to analysis by the PI. The only remaining identifiers to be included in the limited data set include: procedure code, tooth number, zip code, date of birth, race/ethnicity (if available).

Protection Against Risks

The data will then be stored on a stand-alone computer, with no internet connection, locked in a cage to prevent the connection of unwarranted external hard drives. The cage will be bolted to the floor to prevent physical removal of the data containing device. The computer will be locked in an on-campus office. This security protocol is in accordance with the agreement between the Centers of Medicare and Medicaid Services, CHIA and New York University. Furthermore, no attempts will be made to identify individual patients in the data, and in the case where subgroup analysis leads to small sample sizes at risk of identification, data will be aggregated. In addition to this security protocol, the PI is supported by the NYU College of Dentistry Office of Information Security who will establish, implement, and test the secure file transfer, storage and back-up.

2.3.2 Potential Benefits

While there may be little to no direct potential benefits to the study subjects, these research findings may benefit other patients and clinicians. These research findings are expected to have the potential increase understanding of endodontic treatment practices. This may lead to identifying areas for reform or improvement, which will hopefully lead to improved clinical practices and treatment outcomes.

This study will address the previous lack of robust findings by applying appropriate analytic methods to novel data from diverse pediatric populations to generate appropriate treatment prevalence and outcome estimates and inform quality measures in endodontics. For example, the proposed study will be able to determine treatment and outcome differences by payer type. These potential disparities are hypothesized to be in treatment timing, expenditures, and value (as assessed by cost and number of adverse events). These would be both novel explorations and findings. These findings have the potential to inform policies that impact the use of public funds.

3 OBJECTIVES

3.1 Study Objectives

Aim 1: Evaluate the prevalence and outcomes of primary root canal therapy of permanent teeth in a pediatric population and determine factors associated with treatment survival using administrative claims data. Clinical characteristics to be studied include: patient sex, age, race/ethnicity, geographic location, insurance type (public vs. private payer), tooth type, practitioner type, time to / type of coronal restoration.

Aim 2: **Explore dental / emergency room (ER) utilization rates and spending associated with teeth that undergo root canal therapy**.

3.2 Study Outcome Measures

Dependent (outcome) variables: The primary outcome is survival of primary root canal therapy. This will be assessed by analyzing the occurrence of adverse events indicating failure: non-surgical re-treatment, surgical re-treatment, or extraction. Secondary outcome is time to final restoration after root canal therapy. Independent variables include patient-level (age at root canal therapy, area-based SES determined by zip-code (high poverty (>20%), education, rural status), clinical-level (final restoration type after root canal therapy), and provider/system-level (endodontist vs. other; payer type; HPSA designation).

4 STUDY DESIGN

The study design is a retrospective, longitudinal, population-based cohort study.

The conceptual model builds on Donabedian's work[46] and the Anderson and Aday Behavioral Model of Health Care Utilization[47] in that we will study primary determinants of health behavior (e.g., patient, clinician, and health system characteristics) and practice patterns themselves (e.g., final restoration type and guideline adherence; intermediate impacts of health behaviors such as time to restoration). Patient and clinician behavioral factors, such as patient compliance, dental care utilization and practitioner clinical decision-making can influence subsequent outcomes such as procedural, downstream treatment and tooth survival. High quality analyses of effectiveness and utilization can aid decision-makers (e.g., clinicians, patients) to improve care quality and patient quality of life while managing healthcare efficiency.

4.1 Characteristics of the Research Population

Data use agreements have been obtained and feasibility analyses have been conducted to include private and public payer claims for children ages 6-18. We will include children ages 6-18 who've had at least one primary root canal therapy on a permanent tooth [CDT codes D3330 (molar NSRCT), D3310 (anterior NSRCT), D3320 (premolar NSRCT)] and have dental care claims data for six months prior to root canal therapy.

4.2 Number of Subjects

Based on the preliminary analysis, a minimum of 70,835 claims for primary root canal therapy in children aged 6-18 will be available for analysis.

4.3 Gender of Subjects

Persons of both genders will be included in the study

Age of Subjects

Persons aged from 06-18 years will be included in this study.

5 STUDY ENROLLMENT AND WITHDRAWAL

This study uses administrative claims for secondary data analysis:

All-payer claims: In the United States, 51% of all children are covered by private dental benefits.[73] Private payer claims will be provided by the all-payer claims database of the Center for Health Information and Analysis (CHIA) of Massachusetts state from 2012-2017. In addition to the claims data relevant to the outlined research project, CHIA will provide patient information such as defined period of continuous enrollment, patient age at time of primary root canal therapy, zip code and as available, demographics including race, ethnicity, and gender.

Public payer claims: In the United States, 39% of all children have dental insurance provided by Medicaid or the Children's Health Insurance Program (CHIP).[73] A data use agreement has been reached with Health Evaluation and Analytics Lab (HEAL) at New York University for access to New York State Medicaid/CHIP claims data (2006-2017) and with the all-payer claims database from CHIA. These data will also include patient information including defined period of continuous enrollment, patient age at time of treatment, zip code and demographics including race, ethnicity and gender.

Additional data
The public and private payer claims data will be merged with 2000 and 2010 US Census data and HRSA's Area Health Resource File by year. Census data will be used to ascertain area-based socioeconomic measures (SES) in patient zip-code area (percentage of residents living below poverty, without a high school education, rural status) using Census year closest to the initial treatment date.[74] HRSA's Area Health Resource File will be used to determine health professional shortage areas by county, representing limited access to dental care.

5.1 Subject Inclusion Criteria

All individuals must meet all of the inclusion criteria in order to be eligible for inclusion in the secondary data analysis

1. Children aged 6-18
2. Inclusion in the all-payer claims data set provided by the Center for Health information and Analysis (CHIA) of Massachusetts or the Heath Evaluation and Analytics Lab (HEAL)
3. had at least one primary root canal therapy on a permanent tooth
4. have dental care claims data for six months prior/ after root canal therapy.

5.2 Subject Exclusion Criteria

1. People not aged 6-18
2. Children 6-18 not included in the data sets provided by CHIA and HEAL
3. Children 6-18 who have not had at least on primary root canal therapy on a permanent

tooth
4. Children 6-18 who do not have dental claims data for six months prior/ after root canal therapy

5.3 Strategies for Recruitment and Retention

Not applicable, this study uses secondary data for analysis

5.4 Subject Withdrawal

Not applicable, this study uses secondary data for analysis

5.4.1 Reasons for Withdrawal

Not applicable, this study uses secondary data for analysis

5.4.2 Handling of Subject Withdrawals

Not applicable, this study uses secondary data for analysis

5.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party. If the study is prematurely terminated or suspended, the principal investigator will promptly inform the IRB and will provide the reason(s) for suspension or termination.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects.
- Insufficient adherence to protocol requirements.
- Data that are not sufficiently complete and/or evaluable.
- Determination of futility.

6 STUDY SCHEDULE

7 ASSESSMENT OF SAFETY

7.1 Data Storage and Confidentiality

Sharing of data generated by this project is an essential part of our proposed activities and will be carried out in several different ways.

1) New secondary data analyses will be published independently from the model results. Due to data use agreements and Federal regulations governing privacy and compliance, however, we are unable to share the data themselves. Fortunately, we will be able to share analytic program code files for statistical software we use for analyses (e.g., SAS, Stata). These can be applied by other investigators to their own datasets.

Safety monitoring for this study will focus on unanticipated problems involving risks to participants, including unanticipated problems that meet the definition of a serious adverse event.

7.1.1 Unanticipated Problems

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.1.2 Serious Adverse Events

Serious adverse events are not possible in this study. This study utilizes secondary data analysis.

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization

- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

7.2 Reporting Procedures

- appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- a detailed description of the adverse event, incident, experience, or outcome;
- an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB and to NIDCR within 1 week of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB and to NIDCR within 2 weeks of the investigator becoming aware of the problem.
- All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

All unanticipated problems will be reported to NIDCR's centralized reporting system via Rho Product Safety:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 919-287-3998
- Product Safety Email: rho_productsafety@rhoworld.com

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231
- International: 919-595-6486

8 STUDY OVERSIGHT

In addition to the PI's responsibility for oversight, study oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of members with expertise in <in consultation with NIDCR, appropriate clinical, statistical, scientific, ethical disciplines will be inserted>. The DSMB will meet <insert time interval> to assess safety, study progress and data integrity for the study. If safety concerns arise, more frequent meetings may be held. The DSMB will operate under the rules of an NIDCR-approved charter that will be approved at the organizational meeting of the DSMB. At this time, most data elements that the DSMB needs to assess will be clearly defined. The DSMB will provide recommendations to the NIDCR.

The investigator will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The PI will review the data for safety concerns and data trends at regular intervals, and will promptly report to the IRB and NIDCR any Unanticipated Problem (UP), protocol deviation, or any other significant event that arises during the conduct of the study.

9 CLINICAL SITE MONITORING

Clinical site monitoring is conducted to ensure that the rights of human subjects are protected, that the study is implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods are maintained. Monitoring for this study will be performed by NIDCR's Clinical Research Operations and Management Support (CROMS) contractor. The monitor will evaluate study processes and documentation based on NIDCR standards and the International Conference on Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP).

Details of clinical site monitoring will be documented in a Clinical Monitoring Plan (CMP) developed by the CROMS contractor, in collaboration with the NIDCR Office of Clinical Trials and Operations Management (OCTOM) and the NIDCR Program Official. The CMP will specify the frequency of monitoring, monitoring procedures, the level of clinical site monitoring activities (e.g., the percentage of subject data to be reviewed), and the distribution of monitoring reports. Some monitoring activities may be performed remotely, while others will take place at the study site(s). Staff from the CROMS contractor will conduct monitoring activities and provide reports of the findings and associated action items in accordance with the details described in the CMP. Documentation of monitoring activities and findings will be provided to the site study team, the study PIs, OCTOM, and the NIDCR. The NIDCR reserves the right to conduct independent audits as necessary.

10 STATISTICAL CONSIDERATIONS

10.1 Study Hypotheses

Aim1:

H1a: Root canal therapy in permanent teeth of children will vary in survival rate and subsequent treatment compared with studies of adults.
H1b: Clinical characteristics will be significantly associated with survival of root canal therapy.
H1c: Disparities in time to coronal restoration, type of coronal restoration, practitioner type, and survival rates will vary by payer type and area-based poverty/education levels.

Aim 2:

H2: Clinical characteristics and frequency of adverse events will be associated with downstream utilization rates and dental spending.

10.2 Sample Size Considerations

A preliminary feasibility analysis was conducted to determine the usability of the data for the proposed research project (see letters of support). Based on the preliminary analysis (outlined below), we will have enough power to carry out this study. Two data sets will be used in the proposed research project: New York State Medicaid/CHIP claims and all-payer Massachusetts State (public and private) claims data. In a preliminary analysis to determine feasibility of the study, one-year counts of root canal therapy procedures were relatively equal for each year. Based on the preliminary analysis, New York State Medicaid/CHIP data had 41,835 claims from 2006-2011, and Massachusetts State data had 29,000 claims from 2012-2017 that met the inclusion criteria. Based on the preliminary analysis, a minimum of 70,835 claims for primary root canal therapy in children aged 6-18 will be available for analysis. A power calculation is not very informative for this study because our primary goal is to estimate a survival curve for the study population. However, a priori power analysis was conducted and shows that the very large sample size is sufficient to compare outcomes for children covered by public insurance with those covered by private insurance using a Cox proportional hazard model.[75] In the case where the true hazard ratio is 1.10 and only 5% of the 70,000 patients experience an event, we would detect a difference 80% of the time. If the proportion of patients with an event increases to 10%, power increases to 98%.

10.3 Final Analysis Plan

Aim 1: The analytic plan follows from the conceptual model focusing on factors associated with the quality of care, treatment options (further explored in Aim 3), and survival of root canal therapy through descriptive and multivariable analyses. To assess our primary outcome, primary root canal therapy survival, we will start with descriptive statistics to describe the number of root canals

in children and the proportion of treatments that survive within 1, 2, and up to (5) years. Each proposed time point is modeled after the adult endodontic literature. Each time point (1,2 and up to 5 years) provides insight on short and long-term survival and allows us to maximize the use of the data set. We will test hypothesis H1A by comparing pediatric population outcomes to estimates from the literature describing adult populations graphically by plotting the estimated survival curves and 95% confidence bands.[20,35,36] Known clinical covariates might affect survival, so we will test hypothesis H1b by applying a Cox proportional hazards model for the outcome of time to survival (tooth/procedure). We will use the same type of model to assess our secondary outcome: time to final coronal restoration. We will also will use survival analyses to evaluate the proportion of adverse events after primary root canal therapy (non-surgical re-treatment, surgical re-treatment, or extraction) at 1, 2, and (5) years. Importantly in all analyses, we will account for censoring due to end of follow-up and clustering by child using robust standard errors, because there is a correlation in treatment success for each root canal in the same child.[76] In addition to evaluating overall outcomes, we will test hypothesis H1C, assessing disparities in care by area-based SES and payer type. We will conduct the same analyses as explained above but incorporate variables for living in a high poverty area, educational attainment and the variable for insurance type (private vs. public).

Aim 2: We will evaluate dental and related medical utilization rates and spending associated with teeth treated with root canal therapy. For analysis of dental utilization, we will capture specific services, including emergency office visits, and costs of additional treatments associated with the root canal-treated tooth, such as adverse events that included re-treatment and/or extraction. Medical utilization will focus on emergency department visits related to oral health diagnoses. We hypothesize that clinical characteristics such as practitioner type, time to final restoration, and type of final restoration will be associated with downstream utilization rates and dental spending. To test this hypothesis, we will use multivariable logistic regression for dichotomous outcomes (e.g., delayed extraction, any extraction) and Poisson regression for count variables (e.g., number of adverse events or oral health-related emergency room visits). For analysis of spending, we will sum expenditures from claims data, update to current year US$, and estimate 1) mean and median costs and 95% confidence intervals by payer type, delayed final coronal restoration, and practitioner type using a t-test, and 2) multivariable generalized linear models using a log link and gamma distribution,[77] accounting for key factors that may be associated with spending, including patient age, tooth type, final restoration type, delay/timeliness of final restoration, and adverse events (defined in Table 1). A final parsimonious model will be chosen based on Hosmer and Lemeshow's goodness of fit test, such that we will include variables having a bivariate association with the outcome at a cutoff of $p<0.20$.

11 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Study staff will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

12 ETHICS/PROTECTION OF HUMAN SUBJECTS

12.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

12.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

12.3 Informed Consent Process

We will not obtain consent for this study. We are seeking a waiver of authorization and consent as we are performing secondary data analysis.

12.4 Exclusion of Women, Minorities, and Children (Special Populations)

Special populations are not excluded from this study.

12.5 Participant Confidentiality

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all data sets maintained by the investigator.

13 DATA HANDLING AND RECORD KEEPING

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

13.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the investigator. All source documents must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems must be reviewed by the investigator or designee.

13.2 Study Records Retention

Study records will be maintained for at least three years from the date that the grant federal financial report (FFR) is submitted to the NIH.

13.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly.

These practices are consistent with investigator and sponsor obligations in ICH E6:

- Compliance with Protocol, Sections 4.5.1, 4.5.2, 4.5.3, and 4.5.4.
- Quality Assurance and Quality Control, Section 5.1.1
- Noncompliance, Sections 5.20.1 and 5.20.2.

All deviations from the protocol must be addressed in study subject source documents and promptly reported to NIDCR and the local IRB, according to their requirements.

14 PUBLICATION/DATA SHARING POLICY

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

We aim to make our results available to the scientific community. Therefore, the findings from this study will be published and presented at national meetings, the most traditional approaches to sharing study results. The results will be presented at the major scientific meetings related to dentistry and health services research including the American Association of Dental Research, AcademyHealth, and the American Association of Endodontists annual meetings.

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