center for health information and analysis

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

I. INSTRUCTIONS

This form is required for all Applicants, Agencies, or Organizations, hereinafter referred to as "Organization", except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. *All Organizations must also complete the Data Management Plan, and attach it to this Application. The Application and the Data Management Plan must be signed by an authorized signatory. 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. Organiations 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.

The Appliciaton and all attachments must be uploaded to IRBNet. All Application documents can be found on the CHIA website.

Information submitted as part of the Application may be subject to verification during the review process or during any audit review conducted at CHIA's discretion.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is received.

A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet. Please be aware that if your research is funded and under that funding you are required to release raw data to the funding source, you may not receive CHIA Data.

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:	Promoting children's oral health: Identifying provider-, practice-, and community-level characteristics associated with delivery of fluoride varnish in medical offices
IRBNet Number:	**1670894**
Organization Requesting Data (Recipient):	RAND Corporation
Organization Website:	**www.rand.org**
Authorized Signatory for Organization:	**Linda Duffy**
Title:	Director, Contracts, Grants and Procurement
E-Mail Address:	grantteam@rand.org
Telephone Number:	(412) 683-2300
Address, City/Town, State, Zip Code:	4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213-2665
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Rose Kerber**
Title:	Research Programmer
E-Mail Address:	kerber@rand.org
Telephone Number:	(617) 338-2059 x8635
Address, City/Town, State, Zip Code:	20 Park Plaza, 9th Floor, Suite 920 Boston, MA 02116
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Ashley Kranz, PhD
Title:	Health policy researcher
E-Mail Address:	akranz@rand.org
Telephone Number:	703-413-1100 x5616
Address, City/Town, State, Zip Code:	1200 S. Hayes Street, Arlington, VA 22202
Names of Co-Investigators:	Andrew W. Dick, PhD Kimberley Geissler, PhD Sarah Goff, PhD, MD
E-Mail Addresses of Co-Investigators:	andrewd@rand.org kgeissler@umass.edu sgoff@umass.edu

IV. PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

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 (or other derived input)
☐ Surveillance ☐ Student research ☐ Utilization review of resources
☐ Inclusion in a product ☐ Other (describe in box below)

Click here to enter text.

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.

Dental caries, commonly called tooth decay, is a preventable, but common disease (CDC Division of Oral Health 2019). There are widespread racial/ethnic inequities in oral health, with non-White children and adults more likely to experience caries and have worse oral health than White children and adults. Oral disorders/dental treatment is the seventh most costly health condition, leading to health care spending of $66.4 billion in 2013 (Dieleman et al 2016). Timely receipt of oral health services is important for promoting oral health. However, rates of dental visits remain low, with only 43% of the US population making a dental visit in 2015 (Manski & Rohde 2017). Challenges to obtaining oral health services include cost, lack of dental benefits, and shortages and uneven distribution of the dental workforce (Bersell 2017; Manski & Rohde 2017; Vujicic et al 2016). For example, only 45.9% of children insured by Medicaid had a dental visit in 2013, compared to 57.1% of privately insured children (MACPAC 2016). Some factors influencing receipt of oral health services are unique to children. For example, children are eligible to receive some preventive oral health services in medical offices (Moyer 2014), but some dentists express reluctance to treat young children (Garg et al 2013) and parental dental utilization has been found to impact children's utilization (Goettems et al 2012).

This study will analyze the Massachusetts All Payer Claims Dataset to identify factors associated with providers' delivery of and individuals' receipt of oral health services. The specific aims of this study are to:

1. ***Describe utilization of oral health services in Massachusetts, including by insurance-type (e.g., private and Medicaid), setting of care (e.g., medical and dental offices and EDs), and timing of care (e.g., time since ED visit for dental problem to dental office visit).***
2. ***Estimate the causal impact of changes in insurance coverage and policies on receipt of oral health services.***
3. ***Examine the mechanisms affecting receipt of oral health services, including provider characteristics (e.g., specialty, years since training), organizational characteristics (e.g., size, patient sharing with other providers), and community characteristics (e.g., rurality, neighborhood SES, dentist supply).***
4. ***Identify organizational strategies and contextual factors that may promote or inhibit delivery of oral health services.*** *(Please note that Aim 4 involves interviewing providers to understand factors that promote or inhibit delivery of oral health services and that the CHIA data will not be used to contact providers for interviews).*

References

Bersell CH. Access to Oral health care: a National Crisis and call for reform. American Dental Hygienists' Association. 2017 Feb 1;91(1):6-14.

CDC Division of Oral Health. Oral Health Surveillance Report, 2019. 2019. Available from: https://www.cdc.gov/oralhealth/publications/OHSR-2019-index.html. Accessed October 5, 2020.

Dieleman JL, Baral R, Birger M, et al. US spending on personal health care and public health, 1996-2013. JAMA. 2016 Dec 27;316(24):2627-46.

Garg S, Rubin T, Jasek J, Weinstein J, Helburn L, Kaye K. How willing are dentists to treat young children?: a survey of dentists affiliated with Medicaid managed care in New York City, 2010. Journal of the American Dental Association. 2013;144(4):416-25.

Goettems ML, Ardenghi TM, Demarco FF, Romano AR, Torriani DD. Children's use of dental services: influence of maternal dental anxiety, attendance pattern, and perception of children's quality of life. Community dentistry and oral epidemiology. 2012 Oct;40(5):451-8.

MACPAC. Medicaid Access in Brief: Children's Dental Services. 2016. Available from: https://www.macpac.gov/wp-content/uploads/2016/06/Medicaid-Access-in-Brief-Childrens-Dental-Services.pdf. Accessed October 5, 2020.

Manski RJ and Rohde F. Dental Services: Use, Expenses, Source of Payment, Coverage and Procedure Type, 1996–2015: Research Findings No. 38. November 2017. Agency for Healthcare Research and Quality, Rockville, MD. Available from: https://meps.ahrq.gov/data_files/publications/rf38/rf38.pdf. Accessed October 5, 2020.

Moyer VA. Prevention of dental caries in children from birth through age 5 years: US Preventive Services Task Force recommendation statement. Pediatrics. 2014;133(6):1102-11.

Vujicic M, Buchmueller T, Klein R. Dental care presents the highest level of financial barriers, compared to other types of health care services. Health Affairs. 2016 Dec 1;35(12):2176-82.

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**: Applicantions must include 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 this 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.*

This study will identify factors associated with providers' delivery of and individuals' receipt of oral health services, which are a key indicators of public health importance. Key results will include an understanding of contributors to receipt of oral health services including individual, provider, practice, and community-level factors. Examples of quantitative indicators that may be produced include adjusted rates of individuals receiving oral health services overall and by payer (e.g., Medicaid vs. commercial insurance) and rates of delivery of oral health services to children in medical offices. These findings can be used to formulate public policy and health care interventions to increase necessary use of oral health services and improve oral health.

VI. DATASETS 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. For more information about APCD Release Versions, 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. Projects that 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 requests are subject to the Data Use Agreement, will require payment of fees for additional Data for Non-Government Entities, and subject to the limitation that the Data can be used only in support of the approved Project.

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

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

2. Select Release Version and years of data requested (Release Versions and years not listed are not available).

☐ **Release Version 7.0**	☒ **Release Version 8.0**
☐ 2013	☒ 2014
☐ 2014	☒ 2015
☐ 2015	☒ 2016
☐ 2016	☒ 2017
☐ 2017	☒ 2018

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:
We require medical claims to examine receipt of oral health services in all delivery settings, including dental and medical offices, emergency departments, and hospitals, and to examine patient sharing among providers and practices. Medical claims will be used to identify office visits in which providers may address oral health and to identify other conditions that may impact an individual's receipt of medical care and oral health services.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:
We require pharmaceutical claims will be used to identify individuals with health conditions that may impact receipt of oral health services and medical care; additionally, this will identify any prescriptions associated with management of oral health conditions.

☒ Dental Claims

Describe how your research objectives require Dental Claims data:
We require dental claims to examine receipt of oral health services in dental offices and to examine patient sharing among providers and practices, including both medical providers and dental providers.

☒ Member Eligibility

Describe how your research objectives require Member Eligibility data:
We require medical eligibility files to determine member eligibility-during claims periods, length of enrollment, member characteristics, and to identify individuals without medical or dental claims.

☒ Provider

Describe how your research objectives require Provider data:
We require provider files to obtain specialty information about providers, links within organizations, and to link medical claims to other datasets for claims without NPI in the original claim.

☒ Product

Describe how your research objectives require Product data:
Information about product will be used for obtaining information about insurance plan enrollment, which will contribute to our analysis of understanding the role of insurance in the provision of oral health services.

VII. DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of CHIA 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 Organizations 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.

a. Geographic Subdivisions

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

☐ 3-Digit Zip Codes (standard)	☒ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: We require 5-digit ZIP code in order to link key community-level information to the dataset in order to better understand the role of these community-level factors in impacting receipt of oral health services. These community-level factors include rurality and community socioeconomic status. 5-digit ZIP codes also allow us to better identify provider practice locations, which is important in understanding information diffusion in communities (e.g., knowledge and experience about oral health services). Please note that our IRB Protocol categorizes 5-digit ZIP Codes as "location and contact information." We will obtain only 5-digit ZIP Codes from the CHIA data and not obtain any contact information.	

b. 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: Service date is required so that we can examine key measures of utilization, including days from ED visits for dental reasons to dental office visit and days from receipt of oral health services in medical office to dental office visit. These measures provide key information about care coordination and using service dates will allow us to calculate these interactions and examine coordination among providers and impacts on oral health services and outcomes.		

c. National Provider Identifier (NPI)

Select *one* of the following options.

☐ Encrypted National Provider Identifiers (standard)	☒ Decrypted National Provider Identifiers***

***** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology:**
We require a decrypted NPI in order to link CHIA Data to NPI-level datasets, as described in Section IX. Linking CHIA Data to NPI-level datasets is important for linking NPIs to medical practices, to allow us to construct practice-level characteristics and identify organizational and practice characteristics impacting receipt of oral health services.

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 study is directly connected to the administration of Massachusetts' Medicaid program, MassHealth, because of our goal to improve access to care and oral health of MassHealth enrollees. MassHealth covers oral health services for both children and adults, including oral health services in medical offices for children. As observed in many states, children enrolled in MassHealth have lower rates of dental visits than children with private dental coverage in Massachusetts and low-income adults report worse oral health than high-income adults in Massachusetts. Our study will examine factors specific to Medicaid in order to identify strategies for improving access to care and oral health of MassHealth enrollees. This includes, for example, understanding the impact of MassHealth allowing delivery of oral health services in medical offices on children's rates of receipt of oral health services and providers' delivery of oral health services and referrals to dentists.

3. Organizations approved to receive Medicaid Data will be required to execute a Medicaid Aknowlegment of Conditions MassHealth may impose additional requirements on applicants for Medicaid Data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

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):

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.

We will utilize datasets for three main purposes (1) assigning providers to organizations (e.g., practices, medical groups) ; (2) adjusting for provider supply, demand for care, and risk; and (3) to enhance the generalizability of the study.

Datasets used for assigning providers to practices

We will link CHIA Data to the **IQVIA office-based physician dataset** using NPI. The purpose of this linkage is to construct provider-, practice-, and organization-level characteristics.

Recognizing that the IQVIA office-based physician dataset may be missing some information, we will utilize other datasets to fill in missing information about organizations and providers. As needed, we will link CHIA Data to the publicly available **CMS National Plan and Provider Enumeration System (NPPES)** using NPI. NPPES provides basic information about providers, organizations, and practices. As needed, we will link CHIA Data to the publicly available **Provider Enrollment, Chain, and Ownership System (PECOS)** using NPI. PECOS is a national electronic database for recording and retaining data on Medicare-enrolled providers. PECOS data contain provider information, such as specialty, gender, practice name and location. As needed, we will link CHIA Data to the **Medicare Data on Provider Practice and Specialty (MD-PPAS)** database using NPI. MD-PPAS assigns Medicare providers to medical practices and allows for the examination of provider-, practice-, and organization-level characteristics.

Datasets used to adjust for provider supply, demand for care, and risk status

We will link CHIA Data to the publicly available **American Community Survey and Census** using provider- and patient 5-digit ZIP codes. The American Community Survey will provide important community-level information about demographics, employment, and housing.

We will link CHIA Data to the publicly available county-level **Area Health Resource File (AHRF)** using provider- and patient 5-digit ZIP codes and a ZIP-county crosswalk. AHRF provides information about county-level supply and demand for healthcare services.

We will link CHIA Data to the publicly available county-level **Behavioral Risk Factor Surveillance Survey (BRFSS)** using provider- and patient 5-digit ZIP codes and a ZIP-county crosswalk. BRFSS is an annual telephone survey that collects data on emerging public health issues, health conditions, risk factors and behaviors, including oral health.

We will link CHIA Data to the publicly available **County Health Rankings** using provider- and patient 5-digit ZIP codes and a ZIP-county crosswalk. County Health Rankings data, from the Robert Wood Johnson Foundation, provide annual measures of county-level health and well-being, including measures of health factors, health outcomes, clinical care, and the physical environment.

We will link CHIA Data to publicly available **Rural-Urban Commuting Area (RUCA) codes** using provider- and patient 5-digit ZIP codes. RUCA codes are from the USDA Economic Research Service and provide 10-levels of rurality at the 5-digit ZIP code-level.

We will link CHIA Data to publicly available **water fluoridation data** from the US Centers for Disease Control and Prevention using patient 5-digit ZIP codes and a ZIP-county crosswalk. If needed, more recent information on water fluoridation will be obtain from the Massachusetts Water Resources Authority. These data provide information on the percentage of the population receiving fluoridated drinking water.

Datasets to enhance generalizability of study

We will also append the CHIA Data to other state-level claims databases from Connecticut, Maine, New Hampshire, and Rhode Island. The purpose of this stacking of datasets is to examine trends in oral health services in a larger population (i.e., 5 states), which will improve the generalizability of our results, and to examine differences across states based on state policy (e.g., state policy related to Medicaid payment for fluoride varnish in medical offices). This will involve appending (stacking) the information from the CHIA Data with all payer claims databases from these other states, rather than merging on additional data about patients in the CHIA Data. We will eliminate individuals living in states other than the state APCD for adjacent states (e.g., remove Maine residents from MA APCD data, removing MA residents from the Maine APCD) before appending these to ensure that we are not double counting individuals. If we examine only the MA APCD data, we will not know if our findings are unique to Massachusetts or if they are relevant to other states. By examining data from multiple states, we can determine which findings may be unique to Massachusetts and which findings may be common in other nearby states. An example of a model to be estimated using these data include examining the likelihood of a child receiving fluoride varnish during a medical visit, conditional on age, practice characteristics (e.g., size, primary specialty), and county characteristics (e.g., dental health professional shortage area, poverty rate), year, and state of residence. This type of model will allow us to examine how larger practice size increases (or reduces) the likelihood of a children receiving fluoride varnish during a medical visit, and if this varies across or within states.

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.

The fields to be used for linkages are described above and include NPI and provider and patient 5-digit ZIP codes.

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.

In the attachment, we describe the types of variables to be included in the final linked analytic file. Brief descriptions of the variables are included below:

Datasets used for assigning providers to practices

The proprietary **IQVIA data** will provide NPI and provider characteristics (e.g., specialty, graduation date) and organization ID and organization characteristics (e.g., 5-digit zip code, size, languages spoken at the organization, average daily patient volume) and allows for the examination of provider-, practice-, and organization-level characteristics.

The proprietary **MD-PPAS data** may be used for this study if we are unable to assign providers to organizations using the IQVIA data. The MD-PPAS data include NPI and provider characteristics and organization ID and allows for the examination of provider-, practice-, and organization-level characteristics.

The publicly available **CMS National Plan and Provider Enumeration System (NPPES) data** may be used for this study if we are unable to assign providers to organizations using the IQVIA data. NPPES provides basic information about providers, organizations, and practices.

The publicly available **Provider Enrollment, Chain, and Ownership System (PECOS) data** may be used for this study if we are unable to assign providers to organizations using the IQVIA data. PECOS data contain provider information, such as specialty, gender, practice name and location.

Datasets used to adjust for provider supply, demand for care, and risk status

The following datasets will contribute variables at a geographic level (county or zip code) to control for provider supply, demand for care, and risk status: **American Community Survey**, **Area Health Resource File, Behavioral Risk Factor Surveillance Survey, County Health Ranking, Rural-Urban Commuting Area codes,** and **water fluoridation data.** All of these datasets are publicly available.

Datasets to enhance generalizability of study

The proprietary **all-payer claims databases from Connecticut, Maine, New Hampshire, and Rhode Island** will contribute patient information (e.g., sex, age, zip, insurance-type) and information related to procedures (e.g., procedure code, modifier, diagnoses, provider of care, payment, setting of care).

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

As these datasets do not increase the ability or likelihood of identification of individual patients in the linked datasets, these linkages would not jeopardize patient confidentiality. We will not report any results that are based on sample sizes of ten or fewer patients. As discussed in the data security and integrity section, we will take great care to ensure the confidentiality of the data.

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.

The results will be published and presented in peer-reviewed publications and presentations at local and national conferences. All papers will be made publicly available after a 12 month embargo, as required by the NIH Open Access policy.

We will mask cells based on fewer than 11 patients. To ensure this, the investigators will review all potential publications and presentations in advance to ensure that there is no disclosure.

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.

We do not plan to produce separate confidential and public results, although we may share more detailed results to providers or policymakers if interested which may be different from the peer-reviewed publications and presentations produced from the results (e.g., policy memos, briefs). If we prepare these policy memos or briefs, we will ultimately make them publicly available through the investigators' websites. No results will be shared outside the research team that include cells calculated based on fewer than 11 patients to ensure that we do not jeopardize patient confidentiality.

As part of our fourth research aim, we will conduct interviews with medical practices to identify organizational strategies and contextual factors that may promote or inhibit delivery of oral health services. We will not use CHIA data to identify organizations to interview.

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?

Results will be presented as descriptive statistics and regression results. These results will be generalizable to the state. To ensure that individuals cannot be identified, we will ensure that no statistics will be presented for cells that include fewer than 11 individuals.

We may construct maps to illustrate variation in rates of children receiving fluoride varnish in medical offices. These maps will be constructed at the County- or 5-digit ZIP code- level. Again, we will ensure that nothing is reported for cells that include fewer than 11 individuals to protect patient confidentiality.

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?

Click here to enter text.

9. If you have answered "yes" to questions 5, 6, 7 or 8, please provide the name and a description of the products, software, services, or tools.

Click here to enter text.

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?

Click here to enter text.

XI. 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.

Ashley Kranz: Health policy researcher, RAND Corporation
BA, University of Michigan 2006; PhD University of North Carolina 2013; Postdoctoral Fellow: UNC School of Dentistry 2013-2014

Andrew W. Dick: Senior Economist, RAND Corporation
BS, Brown University 1984; PhD Stanford University 1995

Kimberley Geissler: Assistant Professor, School of Public Health and Health Sciences, University of Massachusetts Amherst
BA, Williams College 2006; PhD University of North Carolina 2013; Postdoctoral Fellow: Boston University 2013-2014

Sarah Goff, Associate Professor, School of Public Health and Health Sciences, University of Massachusetts Amherst
BS, Yale University 1991; MD, University of Massachusetts Medical School 1996; Postdoctoral Fellow: Robert Wood Johnson Clinical Scholars Program, Yale School of Medicine 2003-2005; Postdoctoral Fellowship, Tufts University Sackler School of Graduate Biomedical Sciences 2011-2013; PhD, University of Massachusetts Amherst 2018

All members of the research team have conducted substantial quantitative analysis with other health insurance claims datasets, including Medicaid claims, Medicare claims, and MarketScan data. Additionally, Dr. Geissler has used the CHIA MA APCD Data extensively since 2013.

Drs. Geissler and Goff at the University of Massachusetts Amherst will not have direct access to the data. Data will be stored and analyzed at RAND. Drs Geissler and Goff will only review data with cells sizes of more than 11 patients.

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.)

XII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization 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:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

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

Click here to enter text.

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.

Click here to enter text.

3. Will the agent or contractor have access to and 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 #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

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

Click here to enter text.

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.

Click here to enter text.

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]

XIII. 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.

Organizations 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) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) 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 (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	DocuSigned by: Linda Duffy 12F74DAD64B54E3... Drag signature image here or delete and physically sign
Printed Name:	**Linda Duffy**
Title:	Director, Contracts, Grants and Procurement
Date:	December 17, 2020

Appendix. Data sources and variables to be linked to CHIA data					
Dataset	**Public or proprietary data?**	**Variable**	**Level***	**Variable in CHIA data used for linkage**	**Purpose**
Claims data from CT, ME, NH, RI	Proprietary	Patient information (e.g., sex, age, zip, insurance-type)	Patient	Not linked to CHIA patient level data, stacked	To examine receipt of oral health care across subgroups in a larger, more generalizable sample
Claims data from CT, ME, NH, RI	Proprietary	Procedure and related information (e.g., modifier, diagnosis, provider of care, payment, setting of care)	Patient	Not linked to CHIA patient level data, stacked	To examine receipt of oral health care in a larger, more generalizable sample.
IQVIA	Proprietary	NPI and provider characterisitcs (e.g., specialty, graduation date)	Provider	NPI	To link providers to practices and fill in any missing info in CHIA data.
IQVIA	Proprietary	Organization ID and characteristics (e.g., 5-digit zip code, size, languages spoken at org, average daily patient volume, accepting new patients)	Organization	NPI	To assign providers to practices and examine the role of organizational-level factors and oral health care.
MD-PPAS	Proprietary	NPI and provider characterisitcs (e.g., specialty, age, graduation date)	Provider	NPI	To link providers to practices and fill in any missing info in CHIA data.
MD-PPAS	Proprietary	Practice ID (e.g., TIN)	Organization	NPI	If IQVIA is unsuccessful, may use to assign providers to practices and examine the role of organizational-level factors and oral health
PECOS	Public	NPI and provider characterisitcs (e.g., gender, specialty)	Provider	NPI	To link providers to practices and fill in any missing info in CHIA data.
PECOS	Public	Practice name and location (5-digit zip code)	Organization	NPI	If IQVIA is unsuccessful, may use to assign providers to practices and examine the role of organizational-level factors and oral health
NPPES	Public	NPI and specialty	Provider	NPI	To link providers to practices and fill in any missing info in CHIA data.
NPPES	Public	Practice name and location (5-digit zip code)	Organization	NPI	If IQVIA is unsuccessful, may use to assign providers to practices and examine the role of organizational-level factors and oral health

Dataset	Public or proprietary data?	Variable	Level*	Variable in CHIA data used for linkage	Purpose
Area Health Resource File	Public	Dental HPSA	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare supply
Area Health Resource File	Public	Primary care HPSA	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare supply
Area Health Resource File	Public	Total dentists	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare supply
Area Health Resource File	Public	Total physicians (overall & by specialty)	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare supply
Area Health Resource File	Public	Total nurses	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare supply
Area Health Resource File	Public	Total community health centers (overall & by type)	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare supply
Area Health Resource File	Public	Total area in square miles	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare supply
American Community Survey	Public	Population (overall, by age, by race)	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare demand and risk status
American Community Survey	Public	% with insurance (by type)	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for healthcare demand and risk status
American Community Survey	Public	Overcrowded housing	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
American Community Survey	Public	Poverty rate	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk, included in composite measure of neighborhood SES
American Community Survey	Public	Unemployment rate	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk, included in composite measure of neighborhood SES
American Community Survey	Public	Educational achievement	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk, included in composite measure of neighborhood SES
American Community Survey	Public	Receipt of public assistance	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk, included in composite measure of neighborhood SES
American Community Survey	Public	Median household income	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk, included in composite measure of neighborhood SES
American Community Survey	Public	% female-headed households with children	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk, included in composite measure of neighborhood SES
Behavioral Risk Factor Surveillance Survey	Public	% with dental visits	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
Behavioral Risk Factor Surveillance Survey	Public	Self reported oral health	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk

Dataset	Public or proprietary data?	Variable	Level*	Variable in CHIA data used for linkage	Purpose
Behavioral Risk Factor Surveillance Survey	Public	% with chronic diseases	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
County Health Rankings	Public	Food environment index	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
County Health Rankings	Public	Participation in free and reduced price lunch	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
County Health Rankings	Public	Engagement in health behaviors	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
County Health Rankings	Public	Mortality	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
Water fluoridation data	Public	% residents with fluoridated drinking water	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
Rural-Urban Commuting Area codes	Public	10-level measure of rurality	Geographic	Patient/Provider 5-digit ZIP Code	Adjust for risk
*Levels include patient, provider, organization, and geographic.					

RAND HUMAN SUBJECTS PROTECTION COMMITTEE

CHAIR
SANDRA H. BERRY

COORDINATORS
DANIEL CHUNG
KEVIN COLLINS
CAROLYN TSCHOPIK
SYLVIE A. O'NEIL

1776 MAIN STREET
P.O. BOX 2138
SANTA MONICA, CA
90407-2138

TEL (866) 697-5620
hspcinfo@rand.org

APPROVAL

July 30, 2020

Ashley Kranz
Santa Monica

5616
akranz@rand.org

Dear Ashley Kranz:

On 7/30/2020, the HSPC reviewed the following submission:

Title of Study:	Promoting children's oral health: Identifying provider-, practice-, and community-level characteristics associated with delivery of fluoride varnish in medical offices
Investigator:	Ashley Kranz
Research Unit:	Health Care
Funding:	NIH - NIDCR
HSPC ID:	2020-N0637
Submission Type:	Initial Study
Review Type:	Expedited
Determination Date:	7/30/2020
Continuing Review Required?	No
Expiration Date:	N/A
HSPC Coordinator:	Daniel Chung

The HSPC approved the project on 7/30/2020 in expedited Categories 5 and 7 with a waiver of consent to use the claims data. An amendment is required to submit study materials once developed before data collection activities begin.

Click the "Create Modification/CR" button the approved project's workspace to:

- Add or remove a staff member
- Add a new or revised document
- Make an addition or change to the project

To report a deviation from the approved project procedures or other event, click the "Report New Information (Event)" button from the approved project's workspace.

If you have questions or need additional information, please contact your HSPC Coordinator.

Sincerely,

Daniel H Chung

RAND HUMAN SUBJECTS PROTECTION COMMITTEE

CHAIR
SANDRA H. BERRY

COORDINATORS
DANIEL CHUNG
KEVIN COLLINS
CAROLYN TSCHOPIK
SYLVIE A. O'NEIL

1776 MAIN STREET
P.O. BOX 2138
SANTA MONICA, CA
90407-2138

FWA00003425

TEL (866) 697-5620
hspcinfo@rand.org

APPROVAL

October 26, 2020

To Whom It May Concern:

On 10/26/2020, the HSPC approved the following modification:

Title of Study:	Promoting children's oral health: Identifying provider-, practice-, and community-level characteristics associated with delivery of fluoride varnish in medical offices
Investigator:	Ashley Kranz
Research Unit:	Health Care
Funding:	NIH - NIDCR
HSPC ID:	2020-N0637-MOD-01
Submission Type:	Modification / Update
Review Type:	Expedited
Determination Date:	10/26/2020
HSPC Coordinator:	Daniel Chung

Modification description:
This is a post-funding modification [amendment] that updates the study description and key dates and adds an adult population and study team members. The modification is approved to conduct the secondary data analysis in expedited Category 5 with a waiver of consent for the use of the datasets.

A separate modification is required to conduct interviews with medical proctices staff.

If you have questions or need additional information, please contact your HSPC Coordinator.

Sincerely,

Daniel Chung
HSPC Coordinator

RAND HUMAN SUBJECTS PROTECTION COMMITTEE

CHAIR
SANDRA H. BERRY

COORDINATORS
DANIEL CHUNG
KEVIN COLLINS
CAROLYN TSCHOPIK
SYLVIE A. O'NEIL

1776 MAIN STREET
P.O. BOX 2138
SANTA MONICA, CA
90407-2138

FWA00003425

TEL (866) 697-5620
hspcinfo@rand.org

APPROVAL WITH CONDITION

December 22, 2020

To Whom It May Concern:

On 12/22/2020, the HSPC approved the following modification with a condition:

Title of Study:	Promoting children's oral health: Identifying provider-, practice-, and community-level characteristics associated with delivery of fluoride varnish in medical offices
Investigator:	Ashley Kranz
Research Unit:	Health Care
Funding:	NIH - NIDCR
HSPC ID:	2020-N0637-MOD-02
Submission Type:	Modification / Update
Review Type:	Expedited
Determination Date:	12/22/2020
HSPC Coordinator:	Daniel Chung

Please address the following item in order to obtain full approval:

- The draft DUA is basically a placeholder. The project will need to upload a completed DUA before receiving data.

If you have questions or need additional information, please contact your HSPC Coordinator.

Sincerely,

Daniel H Chung

Daniel Chung
HSPC Coordinator

RAND HSPC Information Online (RHINO)

Date: Tuesday, December 22, 2020 11:47:26 AM Print Close

2020-N0637-MOD-02 View: RAND SF: Modification/CR

Modification / Continuing Review / Study Closure

*** What is the purpose of this submission?**

- ○ Continuing Review
- ● **Modification / Update**

ℹ To change the PI, choose 'Other parts of the study/site' scope

Modification scope:
Other parts of the study

Active Modification For This Study	**Modification Type**

Active Continuing Review For This Study

Continuing Review for Study Fluoride varnish in medical offices

Modification Information

*** Summarize the modifications:**

I have made some minor edits to the protocol based on a request from Massachusetts, from whom we are purchasing data. Edits made to study protocol on 12/17/2020 include:
1. Added project plan task number.
2. Updated DUA for Massachusetts data
3. Updated data management plan for Massachusetts data
4. Updated to indicate that Massachusetts data will not be used to contact providers in MA, added upon request of data owner.
5. Update the data sources
5.A. Added that study may use several publicly available datasets that will be linked to claims data an aggregate/community-level.
5.B. Added that study may use claims data from Connecticut, Maine, New Hampshire, and Rhode Island. Please note that we are not yet at the stage of requesting these datasets, so we don't yet have DUAs for CT, ME, NH, and RI. These DUAs will be provided before we begin working with the data.

Why are you submitting an Amendment? (Check all that apply)

- Updating document(s)
- Change in sample/enrollment procedures

2020-N0637-MOD-02

View: SF: Redirect to Draft Submission SmartForm

Part 1: Pre-screener

INTRODUCTION

Congratulations on obtaining the "go ahead" for a RAND project and thank you for entering information about it for screening by HSPC. A few questions will determine whether this project requires further HSPC review or not.

The purpose of this first section is to collect descriptive information about your study (project). We will need to have this information on file even if your study is determined to not be under the purview of RAND's Human Subjects Protection Committee (HSPC).

The information you enter here will be shared only with those responsible for human subjects review of the study and with the individuals you designate. We may share this information with human subjects personnel at other institutions who are also responsible for review of this project. Additionally, all HSPC records must be made available to the federal government's Office for Human Research Protections when requested for auditing purposes.

Instructions for completing a pre-screener.

Date application submitted: 7/21/2020 3:26 PM

* 1.1a Project title (Full Title per Contract, Notice of Award or other formal notice of approval):

Promoting children's oral health: Identifying provider-, practice-, and community-level characteristics associated with delivery of fluoride varnish in medical offices

* 1.1b Short title:

Fluoride varnish in medical offices

* 1.1c Brief description:

This proposed mixed-methods study will use claims data to estimate the causal impact of mandatory medical coverage on children’s receipt of preventive oral health services and examine the mechanisms affecting delivery of fluoride varnish in medical offices, and use a qualitative positive deviance approach to identify strategies and contextual factors promoting or deterring medical providers’ delivery of fluoride varnish.

* 1.1d Principal Investigator:

Ashley Kranz (akranz@rand.org) Refresher Course - Expires 9/6/2021

1.2 Co-Principal Investigator (if applicable):

* 1.3 Who is the best person to contact if we need to follow up with additional information about this study?

Ashley Kranz (akranz@rand.org) Refresher Course - Expires 9/6/2021

*** 1.4 Current project status:**
Funded

*** 1.4b Project Plan Task (PPT)**
HCAAD082

*** 1.5 Indicate the primary source of funding** whether or not the funding is coming directly to RAND as the prime contractor or grantee. That is, if funding from an agency is being channeled through another organization, check that agency. Check all that apply.

D. National Institutes of Health (NIH)

*** 1.5d Specify the NIH institute:**
H. Other

*** 1.5e Other NIH Institute - Specify:**
National Institute of Dental and Craniofacial Research (NIDCR)

*** 1.6 Research Division/Unit(s) Affiliation: Check all that apply**

D. Health Care

*** 1.7 Is your research division/unit leadership aware of this project and have they signed off on it?**
Yes

1.8 Human Subjects involvement: Are you currently planning to involve people in any of the following ways during the expected duration of this project?

Special Instructions:

Include all tasks you **might** be doing, even if not yet funded or fully designed. To ensure that we are capturing all activities, you will need to enter a response for each activity below.

Below we list types of activities and some examples that are not meant to be comprehensive. If in doubt, select the category and provide additional information below. Each activity selected will create a distinct procedure in Part 4 of the Rhino form, if the full form is required.

Note that your normal interactions with the sponsor office or other offices for project management purposes (e.g., discussions of project approach and methods, briefings, monthly update communications discussions regarding how or where to obtain data) are not considered data collection activities.

*** A Expert Panel**, Delphi/consensus panel or workshop to discuss current or future concepts, methods, systems (e.g., meetings of experts to arrive at shared advice, decisions or recommendations regarding a specified issue). Include studies conducted

using Expert Lens.
Do not plan to do

*** B Table-top or gaming exercises**, including in-person or fully computer based games, where individual level decisions or actions by the participants are recorded.
Do not plan to do

*** C Interviews/discussions** with individuals or groups to gather factual information, personal opinions, or judgments from invited participant(s).
Plan to do

*** D Survey**, including structured questions presented in any mode - Internet/web, phone or in person; paper-pencil or computerized surveys.
Do not plan to do

*** E Focus groups** to gather factual information, personal opinions, or judgments from multiple invited participants.
Do not plan to do

*** F Observation** of public or private behavior (e.g., class, school, or neighborhood observations; systematic observation and recording of interactions at a recruiting or training center)
Do not plan to do

*** G Analysis of Defense Manpower Data Center (DMDC)'s** individual level data files under existing FFRDC data sharing agreements. **Will not merge with other data sources.**
Do not plan to do

*** H Analysis of DMDC data merged with other data.** (e.g., Status of Forces survey, Social Security Administration data).
Do not plan to do

*** I Analysis of OTHER previously collected person-level data sets.** Includes public and private data. Data may or may not be identifiable (e.g., educational, personnel, criminal, military (not DMDC), medical records, or other previously collected individual-level data). May include merged dataset.
Plan to do

*** J Analysis of social media or other 'big data'** sources whether public or not (e.g., twitter, Facebook, blogs) at the level of the individual person or that can be linked to individuals.
Do not plan to do

*** K Administering tests or assessments** related to education, training, or other topics.
Do not plan to do

*** L Psychological tests** or assessments.
Do not plan to do

*** M Physical exams or measurements**, including biometric screenings (height, weight, hip, waist, body fat, fitness level, blood pressure, glucose test, etc.).
Do not plan to do

*** N Social behavioral or other interventions**, whether randomized or not - any change in subject's situation or environment intentionally caused by the project (e.g., effects of innovative educational practices on learning, effects of training or new procedures on performance, assignment to experimental condition, or pilot/demonstration programs).
Do not plan to do

*** O Clinical or psychological treatment or intervention** (e.g., effects of cognitive behavioral therapy on post-traumatic stress disorder).
Do not plan to do

*** P Specimen collection** such as blood, urine, hair, buccal swab or other material for testing including genetic testing.
Do not plan to do

*** Q Other types of data collection activities?** Please describe your other research activities.
Do not plan to do

Part 3B: Basic study information

STUDY BASICS

*** 3.1 Title of study**

Promoting children's oral health: Identifying provider-, practice-, and community-level characteristics associated with delivery of fluoride varnish in medical offices

*** 3.2 Brief summary or abstract.** Note: this was populated from question 1.1c on the pre-screener. Using this information please provide a brief summary or abstract of the study. Describe its purposes, study methods (i.e., participants, procedures, data sources), and expected results.

Dental caries, commonly called tooth decay, is a preventable, but common disease (CDC Division of Oral Health 2019). There are widespread racial/ethnic inequities in oral health, with non-White children and adults more likely to experience caries and have worse oral health than White children and adults. Oral disorders/dental treatment is the seventh

most costly health condition, leading to health care spending of $66.4 billion in 2013 (Dieleman et al 2016). Timely receipt of oral health services is important for promoting oral health. However, rates of dental visits remain low, with only 43% of the US population making a dental visit in 2015 (Manski & Rohde 2017). Challenges to obtaining oral health services include cost, lack of dental benefits, and shortages and uneven distribution of the dental workforce (Bersell 2017; Manski & Rohde 2017; Vujicic et al 2016). For example, only 45.9% of children insured by Medicaid had a dental visit in 2013, compared to 57.1% of privately insured children (MACPAC 2016). Some factors influencing receipt of oral health services are unique to children. For example, children are eligible to receive some preventive oral health services in medical offices (Moyer 2014), but some dentists express reluctance to treat young children (Garg et al 2013) and parental dental utilization has been found to impact children's utilization (Goettems et al 2012).

This study will analyze health care claims data to identify factors associated with providers' delivery of and individuals' receipt of oral health services. The specific aims of this study are to:

1. Describe utilization of oral health services, including by insurance-type (e.g., private and Medicaid), setting of care (e.g., medical and dental offices and EDs), and timing of care (e.g., time since ED visit for dental problem to dental office visit).
2. Estimate the causal impact of changes in insurance coverage and policies on receipt of oral health services.
3. Examine the mechanisms affecting receipt of oral health services, including provider characteristics (e.g., specialty, years since training), organizational characteristics (e.g., size, patient sharing with other providers), and community characteristics (e.g., rurality, neighborhood SES, dentist supply).
4. Identify organizational strategies and contextual factors that may promote or inhibit delivery of oral health services using a qualitative positive deviance approach.

3.3 RAND Principal Investigator and Co-Principal Investigator:

* **Principal Investigator:** Ashley Kranz (akranz@rand.org) Refresher Course - Expires 9/6/2021

Co-Principal Investigator (if any):

* 3.4 Does any key staff member have a financial interest related to this research?

No

* 3.5 Do you have a protocol, proposal, or project description to upload? (If yes, you can upload the document below or at the end of this form in Part 7).

● **Yes** ○ No

Protocol Documents:

Document	Category	Date Modified	Document History

View	FV Technical Proposal(0.01)	IRB Protocol	7/23/2020	History
View	FV Proposed Aims(0.01)	IRB Protocol	7/21/2020	History

*** 3.6 Has this project already had a scientific review-that is, a review of the adequacy of the study design?** Check all that apply.

Yes - by funder's proposal review committee

3.7 Who is the intended audience for the results of this study? Where and in what form will you disseminate results?

*** Who is the intended audience for the results of this study:**

Researchers, policymakers, medical and dental providers

*** Where and in what form will you disseminate results?**

Peer reviewed journal articles and research presentations

STUDY FUNDING SOURCES

*** 3.8 Indicate the primary source of funding whether or not the funding is coming directly to RAND as the prime contractor or grantee. That is, if funding from an agency is being channeled through another organization, check that agency. Check all that apply**

Selection	Name
D.	National Institutes of Health (NIH)

*** 3.8d Specify the NIH institute:**

H. Other

*** 3.8d1 Other - Specify:**

National Institute of Dental and Craniofacial Research (NIDCR)

RESEARCH OVERVIEW - DATES

The dates below should cover the entire project and all population-procedure study components. Please provide the dates below based on your best estimates at this time. These dates should be taken from the contract, grant, or statement of work when possible.

Start Dates

*** 3.9 Project Start Date.** Grant and non-FFRDC research should use the award date as the project start date. FFRDC research should use the date on which the project task number was opened. Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.

8/14/2020

*** 3.9a Please explain any date uncertainties below, if applicable.**

Not applicable

*** 3.10 Anticipated Data Acquisition Start Date.** (*Note: this should include pilot/pretest activities).* Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.

2/3/2021

*** 3.10a Please explain any date uncertainties below, if applicable.**

Uncertain when we will receive claims data.

End Dates

*** 3.11 Anticipated Data Acquisition End Date.** Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.

5/31/2024

*** 3.11a Please explain any date uncertainties below, if applicable.**

Not applicable

*** 3.12 Project End Date.** Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.

5/31/2024

*** 3.12a Please explain any date uncertainties below, if applicable.**

Not applicable

RESEARCH OVERVIEW - EXTERNAL ORGANIZATIONS COLLABORATING IN THE RESEARCH

This section of the study form asks questions about other institutions that are participating in human subjects research for this study. All institutions participating in the research must undergo human subjects review either by the institution's own institutional review board (IRB - the HSPC is RAND's IRB) or by deferring to the IRB of another institution (including RAND).

*** 3.13 Are there other institutions besides RAND involved in this study?**

● **Yes** ○ No

*** 3.13a Are you suggesting that RAND should defer to another institution's IRB for this study?**

○ Yes ● **No**

*** 3.13a1 Is RAND the only direct recipient of funding for this project?**
Yes

List each institution involved in any aspect of this study. Click the Add button below to add an institution and fill in all of the required information for that institution. Repeat for each institution.

External Organizations:

Name	Involved Activities	FWA Available?
University of Massachusetts Amherst	Collecting data (surveys, interviews, focus groups, record abstraction, observations, biometric measurements, etc) Sharing responsibility for research design, data analysis, and/or interpreting and reporting results	Yes

*** 3.13i How do you think IRB review should be conducted for this project? RAND HSPC will review your suggested approach and consult with you if needed to make a decision.**
By RAND HSPC as Single IRB/IRB of record

Paperwork Reduction Act (PRA) Determination
To avoid overburdening the public with federally sponsored data collection, the Paperwork Reduction Act (PRA) of 1995 requires that U.S. federal government agencies obtain Office of Management and Budget (OMB) approval before requesting or collecting most types of information from the public. To determine if your study might be required to obtain OMB approval prior to the start of data collection, please answer the following questions. For additional information about PRA requirements, check: Introducing: A guide to the Paperwork Reduction Act

*** 3.14 Is your research directly sponsored by a Federal Agency-that is, RAND is receiving the funding from that agency?**
Yes

*** 3.15 Is your research funded under a Contract or Cooperative Agreement?**
No

Proprietary Data

*** 3.17 Could the research involve proprietary information (i.e., trade or business information that belongs to an organization)? Note RAND has policies regarding the handling of proprietary information. Please review the policies on the intranet page before acquiring any such information.**

- (●) Yes
- ( ) No
- ( ) Don't know

*** 3.17a If 'Yes', please describe the proprietary data you plan to acquire.**

All Payer Claims Datasets from Massachusetts, Connecticut, Maine, New Hampshire, and Rhode Island; IQVIA office-based physician dataset; Medicare Data on Provider Practice and Specialty (MD-PPAS) database.

Non-Disclosure Agreement

*** 3.18 Are you required to sign a Non-Disclosure Agreement? Note: All Non-disclosure Agreements need to be signed by RAND Contracts (Director, Financial Operations and not solely by a RAND employee or other Associate). See link to finance staff page.**

- ( ) Yes
- (●) No
- ( ) Don't know

Private Health Information (HIPAA)

*** 3.19 Will private health information (e.g., medical records, health-related administrative data, health insurance claims, pharmaceutical data) be acquired?**

Yes

*** 3.19a Who will the private information be acquired from? Check all that apply**

Data Aggregators

*** 3.19b Does all of the private information to be acquired for this research fall under HIPAA?**

- ( ) Yes
- (●) No
- ( ) Don't know

Agreements for Obtaining Data

*** 3.20 Are you required to have one or more written Data Use Agreements to acquire data for this study? Note: All Data Use Agreements need to be signed by RAND Contracts (Director, Financial Operations) and not solely by a RAND employee or other Associate). See link to finance staff page.**

- (●) **Yes**
- ( ) No

*** 3.20a Is the Data Use Agreement available to upload to RHINO now, even in draft form?**

- (●) **Yes**
- ( ) No

*** 3.20b Please provide the following details about your Data Use Agreement(s).**

Data Providers	Data Elements
Massachusetts Center for Health Information and Analysis (CHIA)	health care enrollment files and claims data

3.20c You can upload the Data Use Agreement or here or other paperwork in Part 7 (Project Documents).

	Document	Category	Date Modified	Document History
View	Draft Massachusetts data management plan(0.01)	Data Use Agreements	10/26/2020	History
View	Massachusetts DUA - Draft(0.01)	Data Use Agreements	10/26/2020	History

Restrictive Conditions to Acquire/Access Data

*** 3.21 Are any of the data to be acquired or accessed available only under certain restrictive conditions (e.g., the data provider requires signing of a data use agreement or requires expedited or full committee review by the HSPC before the data will be released to the study)?**

- (●) Yes
- ( ) No
- ( ) Don't know

*** 3.21a If 'Yes', what are the restrictions?**

Signed data use agreements are needed to acquire data.

Vulnerable Populations

*** 3.22 Please indicate whether any of the following vulnerable**

populations will be intentionally and knowingly included in the research. Check all that apply. Click on a category to preview Findings that HSPC might need to make.

A. Children/minors (answer follow-up question below)
G. Economically or educationally disadvantaged individuals

*** 3.22a Please describe the population and ages for 'Children/minors'** We are conducting a secondary data analysis of children receiving oral health services, paid by private or public insurers, including children aged 6 months to 18 years of age.

Parental Consent and Child/Minor Assent Procedures
Check this link **for HSPC guidance about consent forms and procedures.**

*** 3.23b1 Parent consent method:**
Don't plan to obtain parent consent - please explain why you feel it is not necessary to obtain parental consent in the comment box below.

*** 3.23b2 Comments/explanation:**
We are conducting a secondary data analysis of children receiving oral health services using de-identified data. We do not have names or contact information, making it impossible to obtain consent.

*** 3.23b3 Child/minor assent method:**
Will not obtain child/minor assent (e.g., child is too young to consent or not cognitively able or you have other reasons). Please explain your rationale for not obtaining child/minor assent in the comment box below.

*** 3.23b4 Comments/explanation:**
We are conducting a secondary data analysis of children receiving oral health services using de-identified data. We do not have names or contact information of children or parents, making it impossible to obtain consent.

*** 3.23b5 Who will implement procedures to obtain parent consent and child/minor assent and how will this be carried out?**
We are conducting a secondary data analysis of children receiving oral health services using de-identified data. We do not have names or contact information of children or parents, making it impossible to obtain consent.

*** 3.23b6 Specify the geographical location of the parents and children/minors.**
Massachusetts, Connecticut, Maine, New Hampshire, and Rhode Island.

*** 3.23b7 Are you aware of any relevant international, federal, or state laws or school policies/practices that govern how parental consent and child/minor assent must be carried out with your study population?** Check all that apply
E. Don't know

Exclusion Criteria

*** 3.24 Are you going to intentionally exclude anyone from the study procedures because of gender, racial/ethnic group, or language fluency? If Yes: please explain by study procedure who you are going to intentionally exclude on the basis of gender, race/ethnic group, or language fluency and why.**

- ○ Yes
- ● **No**

*** 3.25 Are there additional criteria for excluding individuals from the study procedures that are not described above (such as minimum time in current job, specific health condition, cognitive impairment, literacy)? If Yes: please explain the additional criteria for excluding individuals from each procedure.**

- ○ Yes
- ● **No**

Deception in Research Procedures

*** 3.26 Does the research involve any form of deception or withholding of explicit information about the research project? For example, this might include mystery shopping protocols or withholding of key information about the research purpose or other forms of deception.**

- ○ Yes
- ● **No**

Merging Data

*** 3.27 Do you plan to merge person-level secondary data with person-level data from other sources (e.g., other existing records, datasets, or interview data from this study)? *Note: Do not include data that will only be used to contact participants but will not be retained in the study data.***

- ● **Yes**
- ○ No

*** 3.27a What other information will be merged with the person-level data? Note: This does not include data that would not be retained in the data file, such as name or telephone number.**

No individual patient-level data will be linked.

We will merge on provider-level information. We will link the claims data to the IQVIA office-based physician dataset using national provider ids (NPIs) - which are publicly available provider identifiers. The purpose of this linkage is to construct provider-, practice-, and organization-level characteristics.

Recognizing that the IQVIA office-based physician dataset may be missing some

information, we will utilize other datasets to fill in missing information about organizations and providers. As needed, we will link claims data to the publicly available CMS National Plan and Provider Enumeration System (NPPES) using NPI. NPPES provides basic information about providers, organizations, and practices. As needed, we will link claims data to the publicly available Provider Enrollment, Chain, and Ownership System (PECOS) using NPI. PECOS is a national electronic database for recording and retaining data on Medicare-enrolled providers. PECOS data contain provider information, such as specialty, gender, practice name and location. These databases provide information on utilization and performance measures. As needed, we will link claims data to the Medicare Data on Provider Practice and Specialty (MD-PPAS) database using NPI. MD-PPAS assigns Medicare providers to medical practices and allows for the examination of provider-, practice-, and organization-level characteristics.

Additionally, the following publicly available datasets will be linked to the claims data at a geographic level (county or zip code) to control for provider supply, demand for care, and risk status: American Community Survey, Area Health Resource File, Behavioral Risk Factor Surveillance Survey, County Health Ranking, Rural-Urban Commuting Area codes, and water fluoridation data from the US Centers for Disease Control and Prevention and the Massachusetts Water Resources Authority. All of these datasets are publicly available.

We will append (by stacking on top of each other) claims databases from five states: Massachusetts, Connecticut, Maine, New Hampshire, and Rhode Island.

*** 3.27b Will merging the data as described above, increase the likelihood that individuals in the dataset might be identifiable by inference (i.e., comparing details in the data with other information to deduce a subject's identity), whether or not you plan to identify them?**

- ○ Yes
- ● **No**

Data Identifiers and Links

*** 3.28 Will RAND (including RAND subcontractors) have the capability to link person-level data to the participants using a link file, crosswalk, descrambling algorithm, or other unique identifiers (e.g., any other unique identifying number, characteristic, code, or information that can be used to identify an individual), even if you don't plan to do this?**

- ● **Yes**
- ○ No

*** 3.29 Will any individuals in the dataset be identifiable by inference (i.e., comparing details in the data with other information to deduce a subject's identity), even if you don't plan to do this?**

- ○ Yes

● **No**

*** 3.28a Please specify the other information that can be used to identify an individual.**

No individual patient-level data will be linked.

We will merge on provider-level information (as noted above in 3.27a). We will link the claims data to the provider-level datasets using national provider ids (NPIs) - which are publicly available provider identifiers. The purpose of these linkages is to construct provider-, practice-, and organization-level characteristics.

Additionally, we will link the claims data to several publicly available datasets at the ZIP or county level to adjust for health care supply, demand for services, and risk.

Destroying Data Identifiers/Link File

*** 3.30 Will the data identifiers or link file obtained by the project ever be destroyed?**

Yes

*** 3.30a When do you estimate the data identifiers or link files will be destroyed?** Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.

5/31/2024

3.30b Please explain any date uncertainties below, if applicable.

Data identifiers will be destroyed at the end of the study.

*** 3.31 Where will the data identifiers and link file be stored?**

Data will be encrypted and stored as dictated by data use agreement.

Part 4A: Research populations & procedures

Tips for completing Populations and Procedures table.

Introduction

If your study has more than one population or procedure, then it has multiple components. To help reviewers understand your study, on the next screen you will be asked to identify the components by associating a population with a procedure in a matrix. Refer to how to structure populations and procedures to see examples of a multiple population-procedure component matrix and a single component matrix.

Populations

4.1 Think about the people involved in your study. Are they discrete groups? Is there one group that has one set of inclusion criteria that doesn't apply to another group? If so, you will need to specify multiple populations, depending on your study. These populations and the

procedures defined below will be used to form a matrix on the next page. When identifying populations, think about the topics listed below and try to combine into one population participants that are very similar and separate into different populations participants that are very different. Topics covered in the population detail section include: Pilot or pretest, inclusion/exclusion, recruitment activities, informed consent, and interventions. **Note: If doing an intervention, it is not necessary to split a population into the control and intervention groups.**

*** 4.1a Specify Populations – Click Add to list a population. To edit, click on the Update button. To delete, click the X.**

Population: Please provide a brief descriptive label to the subject population (e.g., physicians, students, parents).

Children
Medical practices
Adults

[IF MORE POPULATIONS ARE NEEDED, GO BACK TO 4.1a. OTHERWISE, GO TO 4.2]

4.2 Now that you have named the target population(s), please list each research procedure you will use with each population.

Earlier you listed the following research procedures for this study. Please review the list below and update it as needed:

*** 4.2a. Specify Procedures – Click Add to add a procedure. To edit click on the Update button. To delete, click the X while hovering over the procedure row.**

	Procedure Type	Procedure Name
View	C. Interviews/discussions	C. Interviews/discussions
View	I. Analysis of OTHER previously collected person-level data sets	I. Analysis of OTHER previously collected person-level data sets

[IF MORE PROCEDURES ARE NEEDED, GO BACK TO 4.2a. OTHERWISE, GO TO 4B]

Part 4B: Component selection

Select the components (combinations of Populations and Procedures) that apply to your study below:

Selection Components:

Component #	Population	Procedure
6	Adults	I. Analysis of OTHER previously collected person-level data sets
2	Children	I. Analysis of OTHER previously collected person-level data sets
3	Medical practices	C. Interviews/discussions

Part 4C: Population & procedure matrix

SHOW Instructions for how to link populations and procedures to identify the various components of your study.

Please add the following information to the population-procedures matrix for each data collection component:

- Expected number of participants
- Expected start and end dates
- Current status [drop down menu] –filled out by project
  - Ready to upload materials for HSPC approval now
  - Not ready to submit materials for approval
  - Other- Explain
  - No longer plan to do this

Component #	Population	Procedure	Expected Number of Participants	Expected Start Date	Expected End Date	Current Component Status	Completion Status	Approval Status
2	Children	I. Analysis of OTHER previously collected person-level data sets	50,000	11/01/2020	05/31/2024	Ready to upload materials for HSPC approval now	Completed	
3	Medical practices	C. Interviews/discussions	18	Start of Study Year 3	End of Study Year 3	Not ready to submit materials for approval	Completed	
6	Adults	I. Analysis of OTHER previously collected person-level data sets	1,400,000	Upon receipt of Massachusetts data	05/31/2024	Ready to upload materials for HSPC approval now	Completed	

Part 5A: Research participation identifiability

Introduction

In determining potential risks to human subjects, it is important for the HSPC to understand whether individuals involved in the research can be identified by the data you acquire and access. Please answer the questions in this section about the types of identifiers you are collecting for each study population.

You indicated in Part 4 that the following populations are involved in this study:

Research Participation Identifiability

Update with identifiers for each population.

Population	Identifiers
Children	Location and contact information Dates Identification numbers
Medical practices	Location and contact information
Adults	Location and contact information Dates Identification numbers

Part 5B: Data collection

5.1. **Previously you indicated that you plan to do or may do the following activities involving human subjects.** For each of the activities listed below, click the Update button to answer questions about the data collection for that specific activity. The Completion Status indicates "Complete" if you have answered all of the questions for that activity and "Not Completed" if you have not yet answered all of the questions for the activity. The completion status for all activities must be "Completed" before you can submit the SmartForm.

	Procedure Type	Procedure Name	Completion Status
View	C. Interviews/discussions	C. Interviews/discussions	Completed

View	I. Analysis of OTHER previously collected person-level data sets	I. Analysis of OTHER previously collected person-level data sets	Completed

Part 6: Study-level details

Introduction

In this section, please provide additional details about your data collection procedures. Major topics covered are: Benefits, risks, incentives, and costs to study participants; recruitment and consent procedures; study inclusion/exclusion criteria; waivers requested; types of sensitive data acquired or accessed; and other pertinent study level details.

When answering these questions, please include details pertaining to all populations and procedures that you previously listed in the matrix.

I. Population-specific details

The table below lists the populations identified on your study. Click the Update button next to a population to answer the questions for that population. The Status column indicates whether all questions for the given population have been completed. **Note:** these questions are specific to the population. If you have two similar populations (e.g., two populations of students), make sure both populations appear below. If they don't, go back to Part 4 and add the additional populations as necessary.

Population	Completion Status
Children	Completed
Medical practices	Completed
Adults	Completed

II. Study-specific details

Plans to Share Data

*** 6.13 Do you have any plans to share the individual-level data from your study in identifiable or de-identifiable form?**

◯ Yes ● **No**

*** 6.14 Do you have any reason to expect data might be subpoenaed, requested for an administrative procedure or requested by the client?**

◯ Yes ● **No**

Data Safeguarding Plan (DSP)

*** 6.15 Do you have the Data Safeguarding Plan (DSP) for this study ready to upload in draft or final form? Please use the HSPC template here. Note: If you do not have a DSP your HSPC approval of your project may be delayed until a DSP is submitted.**
Yes

You can upload the DSP in Part 7 (Project Documents)

Data and Safety Monitoring Plan (DSMP)

*** 6.16 Does your funder require a Data and Safety Monitoring Plan (DSMP) for your study? The RAND HSPC will make its determination during the review process.**
No – including not yet determined by the HSPC

Audio/Video Recording

*** 6.17 Will the research team be audio or video recording any interaction procedures for any study participants? Note: If you plan to audio or video record any interaction, you will need to prepare an Audio or Video Release Form for participants to sign. See further instructions and a sample template.**
● **Yes** ○ No

*** 6.17a Provide a step-by-step description of the audio or video recording procedures. Specify the study population, how long the recordings will be retained and how the recordings will be used (e.g., training, dissemination, etc.)**
We will obtain consent to record telephone interviews.
Recordings will be retained for the duration of the study, until the final paper using these interviews is published.
Recordings will be used to create transcripts of the interviews, which will be used for qualitative analysis.
Massachusetts claims data will not be used to contact providers.

*** 6.18 Do you have the questions you will be asking participants (e.g., the interview protocol, survey instrument, or focus group guide) in draft or final form or a list of domains or topics to be covered?**
○ Yes ● **No**

Eligibility for IRB Exemptions

*** 6.19 Do you think that your project should be exempt from further**

review based on one of the IRB exemption categories listed below? Note: For additional information about all of the exemption criteria, click here. You may also click the link next to each specific exemption category for additional information. Check all that apply.

None of the above exemptions apply

The HSPC will consider your suggested exemption category(s) in relation to all the information you supply about the study.

Part 7: Study documents

Introduction

In this section, please upload the study documents (in draft or final form) that are ready for HSPC review and approval at this time. Please clearly label each document so the materials can be linked to the population-procedures matrix. Include the name of the study population-procedure, and any other pertinent details (such as study phase, wave, etc.) in the header of each consent document and/or file name so reviewers can link the materials to the research procedures-population matrix you completed in Part 4.

Component #	Population	Procedure
6	Adults	I. Analysis of OTHER previously collected person-level data sets
2	Children	I. Analysis of OTHER previously collected person-level data sets
3	Medical practices	C. Interviews/discussions

Consent forms: Includes adult or parent consent forms, child assent forms, opt out forms, and other informed consent materials (brochures, FAQs, information sheets, scripts, etc.). [Check HSPC website for sample templates for consent forms that you can adapt for your study]

Document Components Date Modified Document History

There are no items to display

Recruitment materials: (add all material to be seen or heard by study participants, including ads, letters, FAQs, information sheets, brochures, email invitations and reminders, telephone scripts, etc.).

Document Components Date Modified Document History

There are no items to display

Questions (questionnaires, interview or focus group guides, observation forms, other data collection forms, etc.):

Document Components Date Modified Document History

There are no items to display

Other attachments:

	Document	Category	Components	Date Modified	Document History
View	Mass_DMP_draft_2020dec.pdf(0.01)	Data Use Agreements	Children Adults	12/17/2020	History
View	Mass_DUA_draft2020dec.pdf(0.01)	Data Use Agreements	Children Adults	12/17/2020	History
View	I.Estrada Citi Training Certificate.pdf(0.01)	CITI or equivalent training certificate		10/26/2020	History
View	DSP__2020Oct26.docx(0.01)	Data Safeguarding Plans	Children Medical practices Adults	10/26/2020	History
View	Kranz_MA_FV_technical_READY_July1.pdf(0.01)	Grant/Proposal	Children Medical practices	7/23/2020	History
View	KRANZ_CITI_certificate_exp2021.pdf(0.01)	CITI or equivalent training certificate		7/23/2020	History
View	Goff citiCompletionReport.pdf(0.01)	CITI or equivalent training certificate		7/23/2020	History

Suggested attachments: Examples are listed below (not exhaustive)

- Data Safety and Monitoring Plan (DSMP)
- Data Safeguarding Plan (DSP)
- Date Use Agreements (DUA)
- IRB Approval Notices from External IRBs
- Individual Investigator Agreements (IIA) for external staff engaged in research
- Human Subjects section of Research Proposals
- Data Security Protocols for external vendors
- FFRDC Project Descriptions (PDs)
- Memorandum of Understanding (MOUs) from external partners/collaborators
- Audio/Video Release Forms
- Adverse Events Reporting Form
- Other relevant documents

Part 8: Conclusion

*** 8.1 Does the proposed study involve any ethical issues not already discussed in the study application?**

◯ Yes ● **No**

8.2 Please enter any other comments or information that you would like to share with the HSPC reviewer that would be relevant to the review.

I have made some minor edits to the protocol based on a request from Massachusetts, from whom we are purchasing data. Edits made to study protocol include:
1. Added project plan task number.
2. Updated DUA for Massachusetts data
3. Updated data management plan for Massachusetts data
4. Updated to indicate that Massachusetts data will not be used to contact providers in MA, added upon request of data owner.
5. Update the data sources
5.A. Added that study may use several publicly available datasets that will be linked to claims data an aggregate/community-level.
5.B. Added that study may use claims data from Connecticut, Maine, New Hampshire, and Rhode Island. Please note that we are not yet at the stage of requesting these datasets, so we don't yet have DUAs for CT, ME, NH, and RI. These DUAs will be provided before we begin working with the data.