Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Governmental Application for Case Mix Data
[Exhibit A: Data Application]

This form is required by all Applicants, except Government Agencies as defined in 957 CMR 5.02. All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the organization. This Application and the Data Management Plan will be used by CHIA to determine if your organization may receive CHIA data. Please be sure the documents are completed fully and accurately. You may wish to consult the Evaluation Guide that CHIA will use to review your documents. Prior to receiving CHIA Data, the organization must execute the Data Use Agreement. You may wish to review that document as you complete these forms. This application should be completed by the Primary Investigator, and must be signed by a party with authority to bind the organization seeking CHIA Data for the purposes described herein.

NOTE: In order for your application to be processed, you must submit the required application fee. Please consult the fee schedule for the appropriate fee amount. A remittance form with instructions for submitting the application fee is available on the CHIA website.

All attachments must be uploaded to IRBNet with your Application. All applications documents can be found on the CHIA website in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name: (Primary Investigator)	Jonathan C. Simmonds, MD
Title:	Physician - Department of Otolaryngology Head & Neck Surgery
Organization Requesting Data: (Recipient)	Tufts Medical Center
Project Title:	On the Etiology of Pierre Robin Sequence: Is there an association with Maternal Substance Abuse?
IRBNet ID:	
Address, City/Town, Zip Code	Tufts Medical Center Attn: Dept of Otolaryngology, 830 Washington Street, Boston, MA 02111
Telephone Number:	617-636-5000
Email Address:	jsimmonds@tuftsmedicalcenter.org
Names of Co-Investigators:	Andrew Scott, MD (Floating Hospital for Children);
Email Addresses of Co-Investigators:	AScott@tuftsmedicalcenter.org;
Original Data Request Submission Date:	
Dates Data Request Revised:	
Project Objectives (240 character limit):	The goal of our project is to use the Massachusett's Center for Health Information and Analysis (CHIA) Acute Hospital CaseMix Database to determine if there are any teratogens such as methadone that are associated with the

	development of Pierre Robin Sequence, what is the prognosis of these patients, and how much does it cost to provide care for them. As previously mentioned, our specific aims are as follows:
Project Research Questions (if applicable) Business Use Case(s):	1. To determine maternal risk factors associated with the development of PRS in order to guide prenatal discussions, especially in patients with a family history of the condition. Our hypothesis is that maternal substance abuse or methadone use will be a risk factor for the development of PRS 2. To analyze the demographics of patients with PRS to see if there is a racial predilection to the condition. 3. To draw correlations between various demographic identifiers and the particular treatment a given patient undergoes in order to provide tailored anticipatory guidance to families of newborns with PRS 4. To determine the cost of care and resource utilization of patients with PRS.

II. PUBLIC INTERST & PROJECT SUMMARY

1. Briefly explain why completing your project is in the public interest.

Pierre Robin Sequence (PRS) describes a combination of symptoms that arise when underdevelopment of the mandible (micrognathia) in-utero causes superior and posterior displacement of the tongue. This displacement, in turn, leads to the development of a cleft palate and tongue base obstruction, which ultimately gives rise to respiratory distress and failure to thrive. It can occur in isolation or in association with a syndrome such as Stickler's syndrome or Marshall's syndrome [1].

When it was initially described in 1934 by Robin, it was considered universally fatal with close to 100% mortality by 18 months of age [2]. Widespread adoption of the ventilator after the polio epidemic ushered in a new wave of neonatal care. This development, in addition to improvement in the surgical technique for tracheostomies, allowed the mortality of PRS to drop to 30% by the 1950's [3]. Today, the mortality for PRS is around 4%. [4]

Although the mortality rate for PRS continues to drop, the morbidity of this condition remains significant. Even with the development of newer surgical treatments such as Tongue-Lip Adhesion (TLA) and Mandibular Distraction Osteogenesis (MDO), the lifelong burden of this disease on patients and their families is considerable. 41.6% of neonates with PRS require enteral feeding while 28.5% of patients require a g-tube [5]. 26.7 to 55.2% require a surgical procedure to relieve their respiratory distress [6, 7]. Around 21% to 34.4% of patients require a tracheostomy [6, 8].

The average cost of care for a patient admitted with a diagnosis of Pierre Robin has been estimated at $20,160, although the true cost of care and the main drivers of this cost have not yet been studied [9]. For many patients and their families, the struggle to cope with and manage the medical, financial and social burden of this condition is lifelong.

Our project will use the Massachusetts Center for Health Information and Analysis's (CHIA) Acute Hospital

CaseMix database to determine if there are any teratogens such as methadone that are associated with the development of Pierre Robin Sequence (PRS) and to determine other factors associated with the prognosis of these patients.

Outcome studies on PRS have been almost exclusively comprised of small case series with limited follow up. Very few have analyzed maternal medical records to determine if there is an association between the development of PRS and maternal substance abuse, and very little data has been released on the cost of care and the long-term outcomes of these patients. The rarity of this condition makes it difficult for individual institutions to perform retrospective studies.

Purchasing and analyzing the CHIA CaseMix database will allow us to pool data from numerous institutions, giving us a sufficiently large sample size to study the pathophysiology of this condition. The project is designed to be easily replicable and our methodology can be readily applied to the study of other craniofacial disorders. In this sense, not only would our project serve the public good in and of itself, but it can also serve as the basis for other high-potential studies in the future.

References

[1] Scott AR, Tibesar RJ, Sidman JD. 2012. Otolaryngologic Clinics of North America 2012; 45: 695-710.
[2] P R. 1934. American Journal of Diseases of Children 1934; 48: 541-547.
[3] Argamaso RV. 1992. The Cleft Palate-Craniofacial Journal 1992; 29: 232-238.
[4] Elzen APMvd, Semmekrot BA, Bongers EMHF, Huygen PLM, Marres HAM. 2001. European Journal of Pediatrics 2001; 160: 47-53.
[5] Scott AR, Mader NS. 2014. The Laryngoscope 2014; 124: 2818-2825.
[6] Smith MC, Senders CW. 2006. International Journal of Pediatric Otorhinolaryngology 2006; 70: 319-324.
[7] Caouette-Laberge L, Bayet B, Larocque Y. 1994. Plastic and Reconstructive Surgery 1994; 93: 934-942.
[8] Tibesar RJ, Scott AR, McNamara C, Sampson D, Lander TA, Sidman JD. 2010. Otolaryngology -- Head and Neck Surgery 2010; 143: 90-96.
[9] Simmonds J, Skirko J, Scott A, The Increasing Birth Prevalence of Pierre Robin Sequence: is there a link to neonatal abstinence syndrome? City: Tufts Medical Center, 2017.

2. Has an Institutional Review Board (IRB) reviewed your project?

☒ 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.

3. **Research Methodology**: Applicants must provide 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. Applications that do not include this methodology statement cannot be reviewed or approved.

III. DATA FILES REQUESTED [*Applicants seeking 2015 data only should skip to Question 2*]

1. *FY 2004 – 2014 Data*: Please indicate the Case Mix files from which you seek data, the Level(s), the year(s) of data requested, and your justification for requesting *each* file. Please refer to the Case Mix Data Specifications for details of the file contents.

CASE MIX FILES	Levels 1 – 6 All Levels contain Core Elements plus the following in each Level	Years Available 2004 - 2014

Hospital Inpatient Discharge Database	☐Level 1: 3 Digit Zip Code, YYYYMM of Admission; Discharge; Significant Procedures	**Year(s) of Data Requested:** 2004-2015
	☐Level 2: 5 Digit Zip Code, Unique Physician Number (UPN), YYYYMM of Admission; Discharge; Significant Procedures	
	☐Level 3: 5 Digit Zip Code, Unique Health Information Number (UHIN), YYYYMM of Admission; Discharge; Significant Procedures	
	☐Level 4: 5 Digit Zip Code, UHIN, UPN, YYYYMM of Admission; Discharge; Significant Procedures	
	☒Level 5: 5 Digit Zip Code , UHIN, UPN, YYYYMMDD of Admission; Discharge; Significant Procedures	
	Please describe how your research objectives require the requested Level of Hosptial Inpatient Discharge data: The inpatient discharge data will allow us to make the initial diagnosis of Pierre Robin Sequence. It will also give us data on the procedures conducted on these patients. The only aspect of level 5 data that we require is the hashed SSN of patients to be able to connect maternal and neonatal records – otherwise Level 3 data is acceptable for our needs. It is imperitive to be able to connect maternal and neonatal records for our analysis as this will give us insight into risk factors for the development of PRS.	
Outpatient Observation Database	☐Level 1: 3 Digit Zip Code, YYYYMM of Admission; Discharge; Significant Procedures	**Year(s) of Data Requested:** 2004-2015
	☐Level 2: 5 Digit Zip Code, Unique Physician Number (UPN), YYYYMM of Admission; Discharge; Significant Procedures	
	☐Level 3: 5 Digit Zip Code, Unique Health Information Number (UHIN), YYYYMM of Admission; Discharge; Significant Procedures	
	☐Level 4: 5 Digit Zip Code, UHIN, UPN, YYYYMM of Admission; Discharge; Significant Procedures	
	☒Level 5: 5 Digit Zip Code , UHIN, UPN, YYYYMMDD of Admission; Discharge; Significant Procedures	
	Please describe how your research objectives require the requested Level of Outpatient Observation data: The outpatient data for our study is important to understand the long-term prognosis of these patients and is required to truly quantify the cost of care involved. For most of these patients, after the initially surgery or treatment, most of the care is outpatient which is why many studies have not been able	

	to report prognostic information. The only aspect of level 5 data that we require is the hashed SSN of patients to be able to connect maternal and neonatal records – otherwise Level 3 data is acceptable for our needs. It is imperitive to be able to connect maternal and neonatal records for our analysis as this will give us insight into risk factors for the development of PRS.	
Emergency Department Database	☐Level 1: 3 Digit Zip Code, YYYYMM of Admission; Discharge; Significant Procedures	**Year(s) of Data Requested:** 2004-2015
	☐Level 2: 5 Digit Zip Code, Unique Physician Number (UPN), YYYYMM of Admission; Discharge; Significant Procedures	
	☐Level 3: 5 Digit Zip Code, Unique Health Information Number (UHIN), YYYYMM of Admission; Discharge; Significant Procedures	
	☐Level 4: 5 Digit Zip Code, UHIN, UPN, YYYYMM of Admission; Discharge; Significant Procedures	
	☒Level 5: 5 Digit Zip Code , UHIN, UPN, YYYYMMDD of Admission; Discharge; Significant Procedures	
	Please describe how your research objectives require the requested Level of Emergency Department data: In a similar fashion to the outpatient database. The emergency department database helps quantify the burden of this disease and gives us a better idea of the effectiveness of certain therapies. Highly morbidy surgeries may lead to a number of trips to the ED - this type of statistic is not typically documented in studies and therefore remains unknown. The only aspect of level 5 data that we require is the hashed SSN of patients to be able to connect maternal and neonatal records – otherwise Level 3 data is acceptable for our needs. It is imperitive to be able to connect maternal and neonatal records for our analysis as this will give us insight into risk factors for the development of PRS.	

2. *FY 2015 Data*: Beginning *with fiscal year 2015, Massachusetts Acute Care Hospital and Case Mix and Charge Data (collectively Case Mix Data) are released in* ***Limited Data Set (LDS) files***. Please refer to the Case Mix Data Specifications for details of the file contents.

Please indicate the Case Mix files from which you seek data, the year(s) of data requested, and your justification for requesting *each* file.

CASE MIX LIMITED DATA SET FILES	Year(s) Of Data Requested Current Yrs. Available in LDS ☐ 2015
☒**Hospital Inpatient Discharge Database**	**Please describe how your research objectives require Inpatient Discharge data:** As mentioned above: The inpatient discharge data will allow us to make the initial diagnosis of Pierre Robin Sequence. It will also give us data on the procedures conducted on these patients, the underlying demographics on these patients as well as the charge data to evaluate cost-effectiveness.
☒ **Outpatient Observation Database**	**Please describe how your research objectives require Outpatient Observation data:** Our study hopes to evaluate all aspects of care for patients with PRS: therefore we feel it is important to evaluate the inpatient, outpatient and emergency department databases to fully understand the long-term prognosis of these patients. For most of these patients, after the initially surgery or treatment, most of the care is outpatient which is why many studies have not been able to report prognostic information.
☒ **Emergency Department Database**	**Please describe how your research objectives require Emergency Department data:** The emergency department database helps quantify the burden of this disease and gives us a better idea of the effectiveness of certain therapies. Highly morbidy surgeries may lead to a number of trips to the ED - this type of statistic is not typically documented in studies and therefore remains unknown..

Sections IV-IX must be completed by all Applicants requesting 2015 data. Applications that <u>only</u> include requests for prior years of data can skip to Section X.

IV. GEOGRAPHIC DETAIL

Limited Data Set files include zip codes in the following formats for CT, MA, ME, NH, RI, VT, and NY only. Please choose *<u>one</u>* of the following geographic options.

☒ 3 Digit Zip Code (Standard)	☐ 3 Digit Zip Code & City/Town ***	☐ 5 Digit Zip Code ***	☐ 5 Digit Zip Code & City/Town ***
***Please provide justification for the chosen level of geographic detail if requesting something other than 3-Digit Zip Code only. Refer to specifics in your methodology:** We feel that the standard geographic detail provided is sufficient for our needs.			

V. DEMOGRAPHIC DETAIL

Please choose *one* of the following demographic options:

☐ Not Requested (Standard)	☒ Race & Ethnicity***

***** If requested please, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:**

Race and ethnic detail is fundamental if one to assess for risk factors and control for confounding variables. As our preliminary data has shown, there appears to be a racial predilection the development of PRS therefore racial data is require for valid statistical analysis.

VI. DATE DETAIL

Please choose *one* option from the following options for dates of admissions, discharges, and significant procedures:

☐ Year (YYYY)(Standard)	☒ Month (YYYYMM) ***	☐ Day (YYYYMMDD)***

*****Please provide justification for the chosen level of date detail if requesting Month or Day. Refer to specifics in your methodology:**

We feel that monthly data on the admission, discharge and procedures is something that will be useful if a demographic analysis occurs. If risk factors or prognostic data appears to influenced by seasonal conditions (croup etc) then the month of the admission and discharge will be important to evaluate.

VII. PHYSICIAN IDENTIFICATION NUMBERS (UPN)

Please choose *one* of the following options for Provider Identifier(s):

☒ Not Requested (Standard)	☐ Hashed ID ***	☐ Board of Registration in Medicine # (BORIM) ***

*****If requested please, provide justification for requesting Hashed ID or BORIM #. Refer to specifics in your methodology:**

We do not require the physician identification number

VIII. HASHED UNIQUE HEALTH IDENTIFICATION NUMBER (UHIN)

Please choose *one* of the following:

☐ Not Requested (Standard)	☒ UHIN Requested ***

***** If requested please, provide justification for requesting UHIN. Refer to specifics in your methodology:**

The UHIN both of the patient and the patient's mother is required for our data analysis. The UHIN of the patient will allow us to track the patient's record between visits and between the inpatient, outpatient and emergency room databases

IX. HASHED MOTHER'S SOCIAL SECURITY NUMBER

Please choose *one* of the following:

☐ Not Requested (Standard)	☒ Hashed Mother's SSN Requested ***

***** If requested please, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology:**

Access to the maternal charts is central to analysis – through this connection, we can analyze whether any maternal factors led to the development of PRS (eg maternal drug use)

We require a way to connect the maternal and neonatal chart **therefore we require either access to patient's hashed UHIN and the maternal UHIN or the patient's hashed SSN and the maternal hashed SSN**.

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

Note: Data linkage involves combining CHIA data with other databases 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 datasets?
   - ☐ Yes
   - ☒ No linkage or merger with any other database will occur

2. If yes, please indicate below the types of database to which CHIA Data 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 level (e.g., American Hospital Association data)
   - ☐ Aggregate Data (e.g., Census data)
   - ☐ Other (please describe):

3. If yes, describe the data base(s) to which the CHIA Data will be linked, which CHIA data elements will be linked; and the purpose for the linkage(s):

N/A

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.

N/A

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

N/A

6**.** Once the linkage/merge is made, what non-MA Case Mix data elements will appear in the new linked file?

N/A

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. 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 display a cell less than 11, and no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

The information gathered from this paper will be strictly disseminated in peer-reviewed journal articles and poster or presentations at professional society meetings. There will be no publication or public reporting of specific providers or hospital systems based on our data nor will it be used for any advertisement or commercial enterprising.

2. Do you anticipate that the results of your analysis will be published and/or publically available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

The results of our paper that are published in peer-review journals will be immediately accessible to subscribers of those journels which are included in the subscriptions of the majority of academic institutions worldwide. We will also provide copies of these articles free of charge upon request to our department for interested parties without access to those subscriptions.

3. Will you use CHIA Data for consulting purposes?
- ☐ Yes
- ☒ No

4. Will you be selling standard report products using CHIA Data?
- ☐ Yes
- ☒ No

5. Will you be selling a software product using CHIA Data?
- ☐ Yes
- ☒ No

6. Will you be reselling CHIA Data in any format?
- ☐ Yes

☒ No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, with a subscription, etc.)?

N/A

7. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.

N/A

8. If you have answered "yes" to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

N/A

XII. APPLICANT QUALIFICATIONS

1. Describe your qualifications (and the qualifications of your co-investigators) to perform the research described.

The primary investigator: **Andrew R. Scott, MD** is an assistant professor of Otolaryngology and Pediatrics at the Floating Hospital for Children at Tufts Medical Center. He is a specialist in the field of craniofacial disorders with numerous publications in peer-reviewed journals. His Trilogical Society Fellowship Candidate's Thesis "Regional variations in the presentation and surgical management of Pierre Robin sequence" [5] received an honorable mention. He is an active member of the American Cleft Palate/Craniofacial Association, the American Academy of Otolaryngology -- Head & Neck Surgery, and is a Triological Society Fellow and a Fellow of the American College of Surgeons. Co-investigator: **Jonathan Simmonds, MD** is a second-year Otolaryngology resident at Tufts Medical Center. He graduated from Tufts University School of Medicine with AOA (Honors) and has authored a number of peer-reviewed publications and presented at numerous nation meetings in Pediatric Otolaryngology focused on data drawn from large nationwide inpatient databases. He is proficient in the use of SAS and healthcare analytics.

2. **Attach** résumés or curricula vitae of the Applicant/principal investigator, and co-investigators. (These attachments will not be posted on the internet.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

Please note: 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.

Provide the following information for all agents and contractors who will work with the CHIA Data. *Add agents or contractors as needed.*

Company Name:	N/A
Contact Person:	
Title:	
Address, City/Town, Zip Code	

Telephone Number:	
E-mail Address:	
Organization Website:	

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

☐ Yes, a separate Data Management Plan **must** be completed by each agent or contractor
☒ No

2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the tasks; and the Organization's oversight of the agent, including how the Organization will ensure the security of the CHIA Data to which the agent has access.

N/A

Company Name:	N/A
Contact Person:	
Title:	
Address, City/Town, Zip Code	
Telephone Number:	
E-mail Address:	
Organization Website:	

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

☐ Yes, a separate Data Management Plan **must** be completed by each agent or contractor
☒ No

2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the tasks; and the Organization's oversight of the agent, including how the Organization will ensure the security of the CHIA Data to which the agent has access.

N/A

XIV. FEE INFORMATION

Please consult the fee schedules for Case Mix Data and select from the following options:

☒ Single Use
☐ Limited Multiple Use
☐ Multiple Use

Are you requesting a fee waiver?

☒ Yes
☐ No

If yes, please refer to the Application Fee Remittance Form and submit a letter stating the basis for your request (if required). Please refer to the fee schedule for qualifications for receiving a fee waiver. If you are requesting a waiver

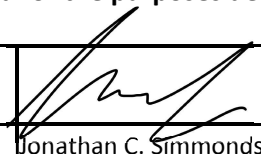
based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

XV. ATTESTATION

By submitting this Application, the Data Applicant attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* is compliant with such use, privacy and security standards. The Data Applicant further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of any CHIA Data provided in connection with an approved Application, including, but not limited to, any breach or unauthorized access, disclosure or use by its agents.

Applicants requesting data from CHIA will be provided with data following the execution of a Data Use Agreement that requires the Data Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

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

Signature: (Authorized Agent)	
Printed Name :	Jonathan C. Simmonds, MD
Title:	Co-investigator, Resident Physician
Signature (Applicant/Primary Investigator)	Andrew R Scott, MD Andrew R Scott, MD (Mar 12, 2017)
Name:	Andrew Scott, MD
Title:	Primary Investigator, Assistant Professor of Pediatric Otolaryngology. Director of the Cleft Lip and Palate Team
Original Data Request Submission Date:	
Dates Data Request Revised:	

Attachments. Please indicate below which documents have been attached to the Application and uploaded to IRBNet:

☑ 1. IRB approval letter and protocol (if applicable)
☑ 2. 1-2 page Research Methodology
☑ 3. Resumes of Applicant and co-investigators
☑ 4. Data Management Plan (including one for each agent of contractor that will have access to or store the CHIA Data at a location other than the Applicant's location, off-site server and/or database)
☑ 5. Fee Remittance Form (including any required documentation if a fee waiver is being requested)