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 <u>957 CMR 5.02</u>. All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the <u>Data Management</u> 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 <u>Data Use Agreement</u>. 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.

<u>NOTE</u>: 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 <u>remittance form</u> 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 <u>CHIA website</u> in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Lauren Cadish, MD
(Primary Investigator)	
Title:	Urogynecologist
Organization Requesting Data:	Providence Health System – Southern California and its
(Recipient)	wholly-owned affiliate Providence Saint John's Health
	Center
Project Title:	Recent Ob/Gyn residency graduates' experience with
	hysterectomy
IRBNet ID:	1018324-1
Address, City/Town, Zip Code	2020 Santa Monica Boulevard, 3 rd floor
	Santa Monica, CA 90404
Telephone Number:	(310) 829-8272
Email Address:	Lauren.cadish@providence.org
Names of Co-Investigators:	Tyler Muffly, MD
Email Addresses of Co-Investigators:	Tyler.muffly@dhha.org
Original Data Request Submission Date:	5/4/17
Dates Data Request Revised:	
Project Objectives (240 character limit):	We aim to describe the median numbers of
	hysterectomies, by modality (vaginal, laparoscopic,
	abdominal) performed by Ob/Gyns in their first five
	years following residency gradaution.
Project Research Questions (if applicable) Business Us	se Case(s): 1. What is the median number of hysterectomies

performed annually by Ob/Gyns who have not completed fellowship training in their first five years following residency graduation?
How is this number broken down by modality of hysterectomy (abdominal, laparoscopic, vaginal)?
3. How does this number compare to more veteran Ob/Gyns?

II. PUBLIC INTERST & PROJECT SUMMARY

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

It is in the public's interest to have well-trained surgeons, and to have those surgeons performing procedures in the way that minimizes patients' surgical risk and shortens their surgical recovery. According to the American Congress of Obstetricians and Gynecologists, vaginal hysterectomy remains the hysterectomy of choice when technically feasible, as it has the lowest morbidity and shortest recovery time. After this, laparoscopic hysterectomy is the second most preferable modality from a patient perspective. Surgeons must also be proficient in abdominal hysterectomy, as not all cases can be performed by a minimally-invasive route, and a complication at the time of a vaginal or laparoscopic case could require the surgeon to convert to laparotomy. In recent years, the number of hysterectomies performed nationally has fallen with increasingly effective options for conservative management of the conditions that serve as indications for hysterectomy. This is to the advantage of our patients, but poses a challenge to us as educators who aim to ensure that graduating Ob/Gyn residents have sufficient surgical experience with hysterectomy to competently perform it as independent practitioners. Ultimately, we believe that Ob/Gyns' performance of these procedures a independent physicians is the best measure of comfort, and whether they will perform hysterectomies as they progress in their careers.

- 2. Has an Institutional Review Board (IRB) reviewed your project?
 - \checkmark Yes, a copy of the approval letter and protocol <u>must</u> be included with the application package on IRBNet
 - ☐ No, this project is not human subject research and does not require IRB review.
- 3. <u>Research Methodology</u>: 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. <u>FY 2004 2014 Data</u>: 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 <u>each</u> file. Please refer to the <u>Case Mix Data Specifications</u> for details of the file contents.

CASE MIX FILES Levels 1 – 6 Years Available

	All Levels contain <u>Core Elements</u> plus the following in each Level	2004 - 2014
Hospital Inpatient Discharge Database	\square <u>Level 1</u> : 3 Digit Zip Code, YYYYMM of Admission; Discharge; Significant Procedures	Year(s) of Data Requested:
	✓ □ Level 2: 5 Digit Zip Code, Unique Physician Number (UPN), YYYYMM of Admission; Discharge; Significant Procedures	-2004-2014
	□ <u>Level 3</u> : 5 Digit Zip Code, Unique Health Information Number (UHIN), YYYYMM of Admission; Discharge; Significant Procedures	
	□ <u>Level 4</u> : 5 Digit Zip Code, UHIN, UPN, YYYYMM of Admission; Discharge; Significant Procedures	
	□ <u>Level 5</u> : 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:	
	We are focused on the experience of recent residency graduates, and will identify these providers with BORIM numbers, necessitating level 2 data. Many hysterectomies are performed on inpatients, necessitating inpatient data.	
Outpatient Observation Database	\square <u>Level 1</u> : 3 Digit Zip Code, YYYYMM of Admission; Discharge; Significant Procedures	Year(s) of Data Requested:
Jutuause	✓ □ Level 2: 5 Digit Zip Code, Unique Physician Number (UPN), YYYYMM of Admission; Discharge; Significant Procedures	-2004-2014
	☐ <u>Level 3</u> : 5 Digit Zip Code, Unique Health Information Number (UHIN), YYYYMM of Admission; Discharge; Significant Procedures	
	□ <u>Level 4</u> : 5 Digit Zip Code, UHIN, UPN, YYYYMM of Admission; Discharge; Significant Procedures	
	□ <u>Level 5</u> : 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:	
	We are focused on the experience of recent residency graduates, and will identify these providers with BORIM numbers, necessitating level 2 data.	

	Many hysterectomies are performed on patients who go home the same day from the hospital or are kept for 23 hour observation, necessitating outpatient data.	
Emergency Department Database	☐ <u>Level 1</u> : 3 Digit Zip Code, YYYYMM of Admission; Discharge; Significant Procedures	Year(s) of Data Requested:
	☐ <u>Level 2</u> : 5 Digit Zip Code, Unique Physician Number (UPN), YYYYMM of Admission; Discharge; Significant Procedures	none
	☐ <u>Level 3</u> : 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	
	☐ <u>Level 5</u> : 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:	

2. <u>FY 2015 Data</u>: 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 <u>Case Mix Data Specifications</u> 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

Userital Impationt [Nibayaa	Place describe how v	our research objectives require	o Innationt Discharge data:
	Discnarge	Please describe now y	Our research objectives requir	e inpatient Discharge data:
Database				
		D	1 1	
☐ Outpatient Observ	ation	Please describe now y	your research objectives requii	re Outpatient Observation data:
Database				
☐ Emergency Depart	ment	Please describe how	your research objectives requir	re Emergency Department data:
Database				
Sections IV-IX must be prior years of data ca			equesting 2015 data. Appli	cations that <u>only</u> include requests for
IV. GEOGRAPHIC DETA	AIL			
		codes in the following	ng formats for CT. MA. ME. I	NH, RI, VT, and NY only. Please choose
one of the following go	-			, , ,
	T 🗆 2 5:			
☐ 3 Digit Zip Code		git Zip Code & own ***	☐ 5 Digit Zip Code ***	☐ 5 Digit Zip Code & City/Town ***
(Standard)			of goographic datail if reque	 esting something other than 3-Digit Zip
Code only. Refer to s			oi geographic detail ii reque	esting something other than 3-Digit Zip
code only. Refer to s	pecifics iii	your memouology.		
V. DEMOGRAPHIC DE	TAIL			
Please choose <u>one</u> of t	the followi	ng demographic opti	ions:	
☐ Not Requested (Sta	ndard)		☐ Race & Ethnicity***	
*** If requested pleas	se, provide	justification for req	uesting Race and Ethnicity.	Refer to specifics in your
methodology:	•			

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VI. DATE DETAIL Please choose <u>one</u> option from the	e following options for dates of	admissions, discharges, and significant procedures:	
☐ Year (YYYY)(Standard)	☐ Month (YYYYMM) *** ☐ Day (YYYYMMDD)***		
***Please provide justification for your methodology:	r the chosen level of date detai	I if requesting Month or Day. Refer to specifics in	
VII. PHYSICIAN IDENTIFICATION N Please choose <u>one</u> of the following		s):	
☐ Not Requested (Standard)	☐ Hashed ID ***	☐ Board of Registration in Medicine # (BORIM) ***	
VIII. HASHED UNIQUE HEALTH IDE Please choose one of the following			
☐ Not Requested (Standard)		Requested ***	
		N. Refer to specifics in your methodology:	
IX. HASHED MOTHER'S SOCIAL SE Please choose <u>one</u> of the following			
☐ Not Requested (Standard)	☐ Hashed Mother's SSN Requested ***		
*** If requested please, provide jumethodology:	ustification for requesting Hasl	ned Mother's SSN. Refer to specifics in your	

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
\square 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)
\square 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):

We are requesting that the decrypted Board of Registration in Medicine (BORIM) number be released as the CHIA data element in lieu of the encrypted UPN. This will enable us to use a crosswalk available from the Board of Registration in Medicine to obtain the providers National Provider Identifier (NPI) number. The NPI number is like a "social security number" for physicians and is required by the Health Insurance Portability and Accountability Act. Specialists in obstetrics and gynecology are listed under a specific taxonomy code in this database. This data is available for download from https://npiregistry.cms.hhs.gov. The entire cohort of practicing OBGYNs is categorized in the National Provider Identification database available. Generalist OBGYN doctors will be identified in the currently up to date, and publicly available NPI database and will be cross-referenced against known subspecialists to ensure that practitioners are not analyzed under more than one category. The linkage will allow for us to identify physicians that fit our inclusion and exclusion criteria.

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.

No algoritm will be used to match the data. The NPI and decrypted license (BORIM) numbers will be matched using a

join feature. If necessary, we will do a hand search of the UPN numbers to determine the NPI number using the
publicly available search tool at The Commonwealth of Massachusetts Board of Registration in Medicine to check
BORIM numbers (http://profiles.ehs.state.ma.us/Profiles/Pages/FindAPhysician.aspx).

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

We are requesting only provider-identifiable data, no patient identifiable data. So we will not be able to identify any individual patients.

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

The new linked file will have the provider's year of medical school and residency graduation, and whether he or she pursued fellowship training. Age, gender, osteopathic or allopathic degree, US or international graduate, name of medical school, year of graduation from medical school, residency program, and business address. The data will come from the NPI database as described above.

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.

We plan to publish the data in aggregate and will restrict cells with less than 11 participants.

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.

We plan for the results of the analysis to be presented at the 2018 joint conference of the American Professors of Gynecology and Obstetrics and the Committee for Resident Education in Obstetrics and Gynecology, and published in the Ob/Gyn medical education literature sometime thereafter. An interested party will be able to obtain our

manuscript for free from the authors. Interested parties will not be given access to the raw data (provider identifiable data) from the analysis.
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.)?
7. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.
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?

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XII. APPLICANT QUALIFICATIONS

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

Drs. Cadish and Muffly are both Obstetrician-Gynecologists who completed fellowships in Female Pelvic Medicine and Reconstructive Surgery. They have an interest in medical education and particularly the way in which residency education is preparing its graduates to be members of the Ob/Gyn workforce. They have manifested this interest by publishing extensively in the scientific literature regarding residency education and surgical outcomes (see attached CVs).

Dr. Cadish currently works as a Urogynecologist at Providence Saint John's Health Center in Santa Monica, California. She also serves as Volunteer Assistant Clinical Professor of Female Pelvic Medicine and Reconstructive Surgery at University of California, Irvine Medical Center, where she completed her fellowship in 2015. Her fellowship thesis was the product of work funded by the Benson Award for Neuromodulation, a national grant she was awarded by the American Urogynecologic Society in 2013. Prior to this, she was a resident at Beth Israel Deaconess Medical Center and held an appointment as Clinical Instructor in Obstetrics, Gynecology, and Reproductive Biology at Harvard Medical School. She is a graduate of the University of Chicago Pritzker School of Medicine.

Dr. Muffly is Assistant Professor of Obstetrics and Gynecology at the University of Colorado School of Medicine. He completed fellowship in Female Pelvic Medicine and Reconstructive Surgery at the Cleveland Clinic Foundation in 2012, and was the recipient of the Rymer Grant bestowed by the Academy of Medical Educators in 2013. He completed his residency in Obstetrics and Gynecology at University of Missouri at Kansas City, and is a graduate of Jefferson Medical College. He is the recipient of teaching awards at both the institutional and national level, and has authored more than fifty academic articles.

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:	Not applicable
Contact Person:	
Title:	
Address, City/Town, Zip Code	
Telephone Number:	
E-mail Address:	
Organization Website:	

_	ccess 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 <u>must</u> be completed by each agent or contractor ✓ □ No 				
▼ □ NO					
2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the talend the Organization's oversight of the agent, including how the Organization will ensure the security of the CHIA					
Company Name:	Not applicable				
Contact Person:					
Title:					
Address, City/Town, Zip Code					
Telephone Number:					
E-mail Address:					
Organization Website:					
1 Will the agent or centractor have a	cooss to ar stara the CHIA Data at a location other than the Applicant's location off				
_	ccess to or store the CHIA Data at a location other than the Applicant's location, off-				
site server and/or database?	agament Dian wayet he completed by each agent or contractor				
-	agement Plan <u>must</u> be completed by each agent or contractor				
⊠ No					
2. Describe the tasks and products as	ssigned to this agent for this project; their qualifications for completing the tasks;				
	he agent, including how the Organization will ensure the security of the CHIA Data				
to which the agent has access.	le agent, including now the Organization will ensure the security of the CHA Data				
to which the agent has access.					
XIV. FEE INFORMATION					
Please consult the <u>fee schedules</u> for 0	Case Mix Data and select from the following options:				
✓ □ Single Use					
☐ Limited Multiple Use					
☐ Multiple Use					
Are you requesting a fee waiver?					
Are you requesting a fee waiver? ✓ □ Yes					
, ¬ 162					
□ No					

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

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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)	Docusigned by: Ufonso Coro
Printed Name :	E30428EC6549402 Alfonso Coro
Title:	Director, Clinical Research
Signature (Applicant/Primary Investigator)	—DocuSigned by:
Name:	Lauren Cadish, MD
Title:	Urogynecologist
Original Data Request Submission Date:	5/4/17
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)