Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Governmental Application for Case Mix Data

This form is to be used by all applicants, except Government Agencies, as defined in 957 CMR 5.02.

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.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Melissa A. Woythaler DO, MS
Title:	Neonatologist
Organization:	Massachusetts General Hospital
Project Title:	Perinatal Morbidity in Late Preterm and Early Term Infants is Associated with Increased Early Intervention Usage in Massachusetts
Mailing Address:	Massachusetts General Hospital 55 Fruit Street Founders 5 Boston, MA 02114
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Names of Co-Investigators:	Vincent C. Smith, Milton Kotelchuk, Susan Manning
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Original Data Request Submission Date:	06/05/2014
Dates Data Request Revised:	09/04/2014, 03/30/2015
Project Objectives (240 character limit)	We are interested in identifying a subpopulation of late preterm and early term infants who are at high risk for requiring Early Intervention. Our current proposal involves looking at admission to level 2/3 nurseries, neonatal morbidities, as well as maternal social factors and later utilization of Early Intervention services. Once these high risk problems are identified, we will categorize possible areas of intervention to improve outcomes in this group. It will also allow us to have better referral criteria to increase services to in need populations.
Project Research Questions (if applicable)	AIM #1: To define NICU usage by late preterm and early term ifnants using three different sources including: (1) the Early Intervention definition from their databse, (2) billing codes provided in the PELL databse, as well as (3) infant length of stay in comparison to maternal length of stay. AIM #2: To compare late preterm infants who are referred and then ultimately test into early intervention services compared to

	those who do not require early intervention services. We will try to categorize possible differences in medical and social factors to help predict which late preterm infants require services.

II. PROJECT SUMMARY

Briefly describe the purpose of your project and how you will use the requested CHIA data to accomplish your purpose.

Late preterm (34-36 6/7 weeks gestation) and early term (37-38 6/7 weeks gestation) infants have been shown to have increased rates of developmental delay, use of Early Intervention Services, and Special Education at school age. However, the majority of late preterm and early term infants test within a normal range. Research to date has not been able to identify a subpopulation of late preterm and/or early term infants that are at higher risk for requiring these services in those who automatic referral is not warranted. This proposed study will be a retrospective cohort study of non-categorically Early Intervention eligible late preterm and early term infants born between the years of 2000-2010. We will first define NICU usage in late preterm and early term ifnants using three definitions of NICU usage including: (1) the Early Intervention defition, (2) using billing codes, and (3) looking at neonatal lenght of stay and whether they are discharged home with Mom. Second, will identify a set of clinical morbidities in this cohort as well as look at different social/maternal factors to see if they are associated with increased Early Intervention usage. Third, we will test whether these medical, social, or a combination of both increase risk for needing Early Intervention Services. This will allow us to identify an at risk group of late preterm and early term ifnants who require Early Intervention Services. If we are able to identify a subpopulation that is at higher risk, we can hone referral criteria to increase Early Intervention services to in need populations.

This proposed study will be a retrospective cohort study of all non-categorically Early Intervention eligible late preterm and early term infants born between the years of 2000-2010. We will divide them into two populations: those who are referred and ultimately test into receiving early intervention services versus those who do not require early intervention services. We will look at their NICU/SCN admission, neonatal morbidities, and social/maternal factors to see if we can identify which infants are at risk for needing services. We hypothesize that late preterm and early term infants who are admitted to level II or III nurseries, have more complicated hospital courses as evidenced by longer length of stays and an increase in diagnostic codes referring to hyperbilirubinemia, respiratory distress syndrome, respiratory failure, feeding immaturity, hypoglycemia, apnea, and thermal instability, as well as lower socioeconomic status and lower maternal education will be referred and test into Early Intervention more frequently.

III. FILES REQUESTED

Please indicate the databases from which you seek data, and the Level(s) and year(s) of data requested.

CASE MIX	Levels 1 – 6	Fiscal Years Requested
Inpatient Discharge	X Level 1 – No Identifiable Data Elements Level 2 – Unique Physician Number (UPN) ☐ Level 3 – Unique Health Information Number (UHIN) ☐ Level 4 – UHIN and UPN Level 5 – Date(s) of Admission; Discharge; Significant Procedures Level 6 – Date of Birth; Medical Record Number; Billing Number **PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL: We are not requesting any identifiable data elements. The DPH with provide calculated length of stay in days. We will use the PELL ID to merge and sort data.**	2000 – 2010 We are not requesting any identifiable data elements. The DPH with provide calculated length of stay in days. We will use the PELL ID to merge and sort data.

Outpatient Observation	☐Level 1 – No Identifiable Data Elements ☐Level 2 – Unique Physician Number (UPN) ☐Level 3 – Unique Health Information Number (UHIN) ☐Level 4 – UHIN and UPN ☐Level 5 – Date(s) of Admission; Discharge; Significant Procedures ☐Level 6 – Date of Birth; Medical Record Number; Billing Number **PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:**	2002 – 2013 Available
Emergency Department	☐Level 1 – No Identifiable Data Elements ☐Level 2 – Unique Physician Number (UPN) ☐Level 3 – Unique Health Information Number (UHIN) ☐Level 4 – UHIN and UPN ☐Level 5 – Date(s) of Admission; Discharge; Significant Procedures ☐Level 6 – Date of Birth; Medical Record Number; Billing Number **PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:**	2000 – 2013 Available

IV. FEE INFORMATION

Please consult the fee schedules for Case Mix data, available at http://chiamass.gov/regulations/#957_5, and select from the following options:

X Single Use
☐ Limited Multiple Use
☐ Multiple Use

Are you requesting a fee waiver?
X Yes
☐ No

If yes, please submit a letter stating the basis for your request. 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.

V. REQUESTS PURSUANT TO 957 CMR 5.04 (Researchers, Payers, Providers, and Provider Organizations)

Please complete only if you are requesting Level 1 (de-identified) Case Mix.

Please describe how you will use such data for the purposes of lowering total medical expenses, coordinating care, benchmarking, quality analysis or other administrative research purposes.

We are interested in identifying a subpopulation of late preterm and early term infants who are at high risk for requiring Early Intervention Services. Late preterm and Early term infants have been shown to have an increased morbidity and mortality at birth. Late preterm infants have been shown to have an increased and significant developmentla delay and learning disabilities compared to term infants. In all research on late preterm infant outcomes there has been a crucial piece of information that has been missing: NICU usage and neonatal morbidities. Previous research has not had hospital data to see if the infants who have more extensive and complicated medical courses require Early Intervention Services. Early Intervention has been shown to be protective and beneficial to the long-term outcomes of preterm infants. These infants would not meet automatic referral criteria because of their gestational age which makes it crucial to identify a subpopulation within late preterm and early term infants who are at higher risk of needing services. This would allow us to have better referral criteria to provide at risk populations with services they need earlier to have the best outcomes possible in the long term.

VI. ALL OTHER REQUESTS - PURPOSE AND INTENDED USE

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

In this country, late preterm births (34-36 6/7 weeks gestation) constitute 8.49% of all births or 71% of all preterm births. Because they are the majority of preterm births, late preterm infants and their long term neurological and school age outcomes are a major public health concern.

Previously, these infants were considered to be small term infants and there were no concerns about delivering a baby during this gestational period. Multiple studies have shown that mortality and morbidity rates of late preterm infants compared to term infants increase as their gestaional age decreases. In fact, most studies have shown a three to ten fold increased risk of mortality and/or morbidity in late preterm infants compared to term controls. These morbidities have been shown to correlate with neurodevelopmental delay in extremely preterm infants; however, this association has never been evaluated in late preterm infants.

Late preterm infants have been shown to have an increased and significant developmental delay and learning disabilities compared to term infants. In all of the research on late preterm infant outcomes, there has been some crucial information that has been missing: NICU usage and neonatal morbidities. All of the research has not had hosptial data to see if the infants who have more extensive and complicated medical courses require Early Intervention Services. Early Intervention has been shown to be protective and beneficial to the long-term outcomes of preterm infants. These infants would not meet automatic referral criteria because of their gestational age which makes it crucial to identify a subpopualtion within late preterm and early term ifnants who are at higher risk of needing Services. This would allow us to have better referral critera to provide at risk populations with Services they need earlier to have the best outcomes possible in the long term.

2. **Attach** a brief (1-2 pages) description of your research methodology. (This description will not be posted on the internet.)

3. Has your project received approval from your organization's Institutional Review Board (IRB)? Please note that CHIA will not review your application until IRB documentation has been received (if applicable).

   X Yes, and a copy of the approval letter is attached to this application.

   ☐ No, the IRB will review the project on _____.

☐ No, this project is not subject to IRB review.

☐ No, my organization does not have an IRB.

4.

VII. APPLICANT QUALIFICATIONS

1. Describe your qualifications to perform the research described or accomplish the intended use of CHIA data.

I have written and published two previous papers on the long-term developmental and school age outcomes of late preterm infants. I am interested in this population because they are considered close to term and that there are no differences from full term infants. However, the data shows differently. Late preterm infants represent the largest part of all preterm births and a good population to have interventions for a better outcome.

2. Attach résumés or curricula vitae of the applicant/principal investigator, key contributors, and of all individuals who will have access to the data. (These attachments will not be posted on the internet.)

VIII. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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

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

☐ Yes

X No linkage or merger with any other database will occur

2. If yes, will the CHIA Data be linked or merged to other individual patient level data (e.g. disease registries, death data), individual provider level data (e.g., American Medical Association Physician Masterfile) , facility level (e.g., American Hospital Association data) or with aggregate data (e.g., Census data)? [check all that apply]

☐ Individual Patient Level Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

☐ Individual Provider Level Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

☐ Individual Facility Level Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

☐ Aggregate Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

3. 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 that algorithm will link each dataset.

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

5. If yes, and the data mentioned above is not in the public domain, please attach a letter of agreement or other appropriate documentation on restrictions of use from the data owner corroborating that they agree to have you initiate linkage of their data with CHIA data and include the data owner's website.

IX. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting.

Publication in professional journal and/or presentation at national meeting after DPH review of the results to make sure they are in compliance with the MDPH data suppression rules.

2. Will the results of your analysis be publicly available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee.

No

3. Will you use the data for consulting purposes?

☐ Yes
X No

4. Will you be selling standard report products using the data?

☐ Yes
X No

5. Will you be selling a software product using the data?

☐ Yes
X No

6. Will you be reselling the data?

☐ Yes
X No

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

7. If you have answered "yes" to questions 3, 4 or 5, please describe the types of products, services or studies.

X. USE OF AGENTS AND/OR CONTRACTORS

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	N/A
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

8. Will the agent/contractor have access to the data at a location other than your location, your off-site server and/or your database?

   ☐ Yes
   ☐ No

   If yes, please provide information about the agent/contractor's data management practices, policies and procedures in your Data Management Plan.

9. Describe the tasks and products assigned to this agent or contractor for this project.

10. Describe the qualifications of this agent or contractor to perform such tasks or deliver such products.

11. Describe your oversight and monitoring of the activity and actions of this agent or subcontractor.

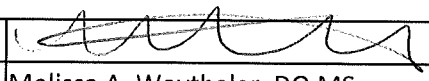
XIII. ASSURANCES

Applicants requesting and receiving data from CHIA pursuant to 957 CMR 5.00 ("Data Recipients") will be provided with data following the execution of a data use agreement that requires the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

Data Recipients are further subject to the requirements and restrictions contained in applicable state and federal laws protecting privacy and data security, and will be required to adopt and implement policies and practices to protect CHIA data in a manner consistent with the requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Data Recipients must promptly notify CHIA of any unauthorized use or disclosure of CHIA data.

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) my organization's ability to meet CHIA's minimum data security requirements; and (3) my authority to bind the organization seeking CHIA data for the purposes described herein.

Signature:	
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Original Application Submission Date:	06/05/2014
Dates Application Revised:	09/04/2014 and 03/30/2015 and 7/8/2015