Part A: Protected Health Information

THE INFORMATION YOU ARE REQUESTING IS CONSIDERED PROTECTED HEALTH INFORMATION IN THAT IT CONTAINS PERSONALLY IDENTIFIABLE DATA. PERSONAL IDENTIFIERS INCLUDE BUT ARE NOT LIMITED TO: NAMES, RESIDENTIAL ADDRESSES AND RESIDENTIAL ZIPCODES. SOCIAL SECURITY NUMBERS ARE NOT INCLUDED ON BIRTH FILES. THE USER WILL ACKNOWLEDGE THAT OTHER DATA FIELDS MAY CONSTITUTE PROTECTED HEALTH INFORMATION, GIVEN THE DEFINITION BELOW:

“Protected health information means any information, whether oral, written, electronic, visual, pictorial, physical, or any other form, that relates to an individual’s past, present, or future physical or mental health status, condition, treatment, service, products purchased, or provision of care, and which (a) reveals the identity of the individual whose health care is the subject of the information, or (b) where there is a reasonable basis to believe such information could be utilized (either alone or with other information that is, or should reasonably be known to be, available to predictable recipients of such information) to reveal the identity of that individual.”

“For example, if a health record contains sufficient information to identify an individual to whom it relates because it provides information which specifically narrows the class of individuals in an aggregate setting (such as an HIV report that contains the race, sex, age, county of residence, date of infection, place of treatment, or other information about an individual in a rural community with limited cases of HIV infection), such record may also be considered identifiable in its existing form, and thus protected health information.”

IF THIS PROTECTED HEALTH INFORMATION IS USED TO IDENTIFY INDIVIDUALS, THE USER SHALL BE AWARE OF THE FOLLOWING TERMS AND REQUIREMENTS FOR USE:

• **Use** means to employ or utilize all or any part of any protected health information for a legitimate public health purpose. Public health agencies are allowed to use protected health information for legitimate public health purposes with minimal restrictions. Uses of such information include transferring information within or among public health agencies that have the authority to acquire the information. Uses do not include disclosing such information to any person outside a public health agency.

• **Legitimate public health purpose** means a population-based activity or individual effort primarily aimed at the prevention of injury, disease, or premature mortality, or the promotion of health in the community, including (a) assessing the health needs and status of the community through public health surveillance and epidemiological research, (b) developing public health policy, and (c) responding to public health needs and emergencies.

• **Public health official** means any officer, employee, private contractor or agent, intern, or volunteer of a public health agency with authorization from the agency or pursuant to law to acquire, use, disclose, or store protected health information.

• **Commercial Uses**: Protected health information shall not be used by a public health agency or public health official for commercial purposes.

• **Deceased Individuals**: Generally, nothing shall prohibit the disclosure of protected health information in a certificate of death, autopsy report, or related documents prepared under applicable laws or regulations.

• **Social Security Numbers**: Not available except on death certificates in approved cases.

THE FOLLOWING REQUIREMENTS FOR USES CONSISTENT WITH ORIGINAL LEGITIMATE PUBLIC HEALTH PURPOSES APPLY:

[a] **In General.** Protected health information shall be used by a public health agency solely for legitimate public health purposes that are directly related to the purpose for which the information was acquired. Providing access to protected health information to any person other than a public health agency or public health official is not a use;
Subsequent Uses. A public health agency may use protected health information for legitimate public health purposes that are not directly related to the original purpose for which the information was acquired only if: The agency’s subsequent use relates directly to a legitimate public health purpose; the use is reasonably likely to achieve such purpose, and the purpose cannot otherwise be achieved as well or better with non-identifiable information.

Research Use. A public health agency or official may use protected health information for public health, epidemiological, medical, or health services research provided that:

1. it is not feasible to obtain the informed consent of the individual who is the subject of the information;
2. identifiable information is necessary for the effectiveness of the research project;
3. the minimum amount of information necessary to conduct the research is used;
4. the research utilizing the protected health information will likely contribute to achieving a legitimate public health purpose; and
5. the information is made non-identifiable at the earliest opportunity consistent with the purposes of the research project and expunged after the conclusion of the project.

IN ADDITION, YOU HAVE THE DUTY TO ADHERE TO THE FOLLOWING IN ORDER TO HOLD INFORMATION SECURE:

Generally. Public health agencies have a duty to acquire, use, and store protected health information in a confidential manner which safeguards the security of the information.

Security Measures. Public health agencies and other persons who are the recipients of protected health information disclosed by any agency, other than the individual (or the individual’s lawful representative) who is the subject of the information, shall take appropriate measures to protect the security of such information, including:

1. maintaining such information in a physically secure environment, including:
   [i] limiting the number of physical places in which such information is used or stored; and
   [ii] prohibiting the use or storage of such information in places where the security of the information may likely be breached or is otherwise significantly threatened;
2. maintaining such information in a technologically secure environment;
3. identifying and limiting the persons having access to such information to those who have a demonstrable need to access such information;
4. reducing the length of time that such information is used or stored in a personally-identifiable form to that period of time which is necessary for the use of the information;
5. eliminating unnecessary physical or electronic transfers of such information;
6. expunging duplicate, unnecessary copies of such information;
7. assigning personal responsibility to persons who acquire, use, disclose, or store such information for preserving its security;
8. providing initial and periodic security training of all persons who acquire, use, disclose, or store such information;
9. thoroughly investigating any potential or actual breaches of security concerning such information; and
10. undertaking continuous review and assessment of security standards.

IF A RECIPIENT OF THESE DATA: BY YOUR SIGNATURE ON THE LAST PAGE, YOU ACKNOWLEDGE THAT YOU UNDERSTAND ALL PRECEDING ITEMS AND THE FOLLOWING STATEMENT, AND AGREE TO USE THE DATA ACCORDINGLY.

"Protected health information contains health-related information about individuals which may be highly-sensitive. This information is entitled to significant privacy protections under federal and state law. The disclosure of this information outside public health agencies in an identifiable form is prohibited without the written consent of the person who is the subject of the information, unless specifically permitted by federal or state law*. Unauthorized
disclosures of this information may result in significant criminal or civil penalties, including imprisonment and monetary damages."

Adapted from the Model State Public Health Privacy Act, August 12, 1999.
LAWRENCE O. GOSTIN, JD, LLD (HON), Georgetown University Law Center, Washington, DC.
* per Health Insurance Portability and Accountability Act of 1996

Part B: Data Use Policy (Created 2.22.02 (revised 1.5.11))

The intent of this policy is to assure the availability of Georgia data to public health researchers for the benefit of Georgia citizens while safeguarding its confidentiality. The policy is to serve the needs of the citizens, the agency and the researcher. The policy will improve communication and coordination by outlining major steps related to release of data as well as to publication and dissemination of the data.

The elements for this policy are:

- All requests for data should be project-specific rather than a blanket request for data, e.g., “birth certificate data for all births between 1996 and 2000.” A blanket request for data should be considered only if
  1) a series of beneficial analyses and/projects are proposed,
  2) it is mutually beneficial and in the best interest of both parties, and
  3) special procedures are developed to safeguard everyone’s interest and concerns.

- All requests should be accompanied by a one-page proposal outlining the objectives, design and analysis of the research, safeguards for assuring the confidentiality of the data, and steps to return or destroy the original and subsequently created data sets. Assurances of confidentiality and ultimate elimination of the data are the responsibility of the requesting agency and assurances are to be provided by that agency. For those investigators who may have prior access to the data from another project, no work on any new project of any kind may be performed without prior approval. The Department of Public Health (hereafter, “DPH”) will attempt to approve all projects within three weeks, but provision of new data sets may take a substantially longer time.

- Before release of the data, the researcher(s) and DPH should discuss and agree upon authorship and responsibilities of authorship. The primary author should sign this authorship agreement that includes authorship, role of authors, rules of communication and other essentials.

- All data released outside DPH should be de-identified or have received IRB approval from DPH. IRB approval/exemption through the requesting agency or other IRB agreed to by DPH will greatly expedite the approval process, and may waive the need for Georgia Department of Public Health IRB application. For policies, procedures and forms visit http://www.odis.dhr.state.ga.us/7000_reg/regulatory.htm

- Before submission for publication or other distribution, DPH shall receive a copy for review and comment. DPH must be given at least three weeks for comment. If a CDC author, this process should occur before submission for CDC clearance.

- After project completion, the researcher(s) agree to at least one presentation of the data to interested people at DPH before publication.

- Depending on the nature of the project proposed, DPH may request additional services of the investigator to assure program benefit to DPH. DPH will make such requests in advance before approval of the request to receive data.
Part C: Data Use Form: Protected Health Information for a Public Health Purpose by Non-DPH Employees.

YOUR DATA REQUEST: Please complete all of the following areas (additional pages may be attached).

Purpose of data request and objectives for use:
Introduction: Between 1980 and 2000, the rural Hispanic population in the United States doubled from 1.5 million to 3.2 million, making Hispanics the most rapidly growing nonmetropolitan (rural) population (Kandel and Cromartie 2004). This trend also coincided with a geographic shift in the Hispanic population away from traditional areas of settlement (the Southwest), and to new areas in the Midwest and the Southeast. There is some work in the public health literature evaluating this access to primary care and proximal risk factors for chronic disease among Midwestern and Southeastern Latinos, but there has been very little study of this population from a broader “population health” perspective. It is not yet clear if patterns of Latino health observed at the national level and in urban settings will also hold true in these relatively new, predominately rural, settings. This study aims to evaluate patterns of adverse birth outcomes (a sensitive measure of the overall health of a population) among Latina women in a non-traditional destination state. We will examine risk of low birth weight, very low birth weight, and preterm birth by comparing urban and rural women, as well as comparing birth outcomes for Hispanic and non-Hispanic mothers.

Data: We will use birth certificates data for all births in Georgia for the most recent five-year period available (2006-2010 or 2007-2011).

Methods: We will evaluate rates of adverse birth outcomes (preterm birth, low birth weight, very low birth weight) among Hispanic women residing in urban and rural parts of Georgia. We will compare their results with those of non-Hispanic women, adjusting for mother’s age, access to prenatal care, and other covariates.

Significance: This study will inform our understanding of the health of a growing population. Understanding the health of rural and urban Latinos in a non-traditional destination state will expand our understanding of Latino health in general.


Design and analysis of the research:
We are asking for microdata abstracted from Georgia birth certificates from 2007-2011.

The purpose of this study is to characterize urban-rural differences in Latino health compared to the non-Hispanic population, and to compare these patterns to those of non-Hispanics. We hypothesize that Hispanic mothers will have lower risk of adverse birth outcomes than non-Hispanic mothers, but that this disparity in risk will be smaller in rural areas.

• Aim 1: To calculate rates of adverse birth outcomes among Hispanic and non-Hispanic women in Georgia.
• Aim 2: To test whether these rates vary between urban and rural areas.

Study Methods:
a. Subject selection
All births in Georgia from January 2007 to December 2011
b. De-identification of subjects

We will need date of birth information initially, but will then classify subjects according to periods of birth, at which point we can fully de-identify the data.

c. Data collection and analysis techniques

We are asking for data abstracted from birth certificates in Georgia between January 2007 and December 2011. Associations between adverse birth outcomes and race/ethnicity and other factors will be modeled using logistic regression.

LIST OF DATA ITEMS (fields, variables). Provide a detailed description of data requested (include geographic area (geographic unit of analysis), and whether by residence or occurrence; time period; age; race; and for any other criteria, please list the specific variables).

<table>
<thead>
<tr>
<th>Geographic Unit of Analysis (Where and what units).</th>
<th>Analysis by:</th>
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<tbody>
<tr>
<td>Example: By County, for Fulton &amp; DeKalb.</td>
<td>X Residence</td>
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<tr>
<td>By County</td>
<td>Occurrence</td>
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<tr>
<td></td>
<td>Both</td>
</tr>
<tr>
<td>Time Period</td>
<td>Ages</td>
</tr>
<tr>
<td>Check if data by Sex are requested</td>
<td>Race group(s)</td>
</tr>
<tr>
<td>Check if data by Ethnicity are requested</td>
<td>X</td>
</tr>
<tr>
<td>e.g. 2000-latest year</td>
<td>all</td>
</tr>
<tr>
<td>2006-latest year</td>
<td>X</td>
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</tbody>
</table>

**List ALL additional Data Items**

- Birth county
- Sex
- Plurality
- Birth order
- Mother’s year of birth
- Mother’s birthplace (state code)
- Mother’s residence (county code)
- Marital status
- Father’s birthplace (state code)
- Father’s year of birth
- Mother’s race
- Mother’s Hispanic ancestry
- Mother’s education
- Father’s race
- Father’s Hispanic ancestry
- Father’s education
- Number terminations
- Date last termination
- Date last menses
- Gestational age clinical estimate
- Date first prenatal visit
- Month prenatal care began
- Number prenatal care visits
- Mother’s total weight gain/loss
- Birthweight
- Apgar score – 1 minute
- Apgar score- 5 minutes
- Congenital anomalies
- Abnormal condition of newborn
- Alcohol use
- Tobacco use

**PROTECTED HEALTH INFORMATION (PHI):** List each PHI data item and justify the use for each item, stating how each item is used to achieve the purpose of your study. Requests for PHI items will not be processed.
without specific justification for inclusion. Protected Health Information items include, but are not limited to: names, dates of birth, certificate numbers, addresses and potentially geographic units smaller than County.

<table>
<thead>
<tr>
<th>PHI Data Items</th>
<th>Intended Use or Reason for this data item (be specific)</th>
</tr>
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<tbody>
<tr>
<td>Child’s date of birth</td>
<td>Conventional demographic methods require date of birth in order to be able to check estimates of rates of adverse birth outcomes against population-level denominators.</td>
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</table>

Safeguards for assuring the confidentiality of the data:

ANALYSTS

The Investigators (Aresha Martinez-Cardoso and Nicole Novak) and faculty advisor (Arline Geronimus), hearafter “Authorized Users,” will work with the data. All have undergone certified IRB training through the University of Michigan and have been made fully aware of the sensitive nature of these data. Support staff at the Population Studies Center (Ricardo Rodriguez, Mark Sandstrom, and Lisa Neidert) will arrange for the secure computing environment and the custody of the data. This team manages over 40 active restricted data contracts and ensures that best practices for the protection of the data are followed.

DESCRIPTION OF THE COMPUTING ENVIRONMENT

All analyses involving sensitive data will be conducted at the University of Michigan’s Institute for Social Research. Data will be analyzed on a stand-alone computer, not connected to the internet. The computer requires a login with a unique user ID and password for each user. A password protected screensaver is in use when logged in (on 5 minute timer). As an added precaution, the BIOS is password protected so that an intruder cannot get access to the PC via a boot disk.

The work area for the project, including the raw data file, is encrypted with Windows encrypting software. The statistical package in use points its temporary work area to this encrypted area rather than the factory defaults.

This operating system of the computer is kept patched with relevant updates. Anti-virus software is in use.

DATA ACCESS AND DATA STORAGE

The data and work files are stored on the PC hard drive. The hard disk is not backed up. The user will back up programs (programming code/syntax only) on a networked drive in case of disk failure. No restricted data or derived data will be stored on a networked drive. At the conclusion of the project, the data and work areas on the hard drive will be erased with ‘secure erase’ software.

The original media are stored in office 1090 ISR (Secure Data Manager, Lisa Neidert’s office).

HARD COPIES

No paper copies of sensitive printouts will be made. Published results will be limited to descriptive statistics and/or statistical models.

DISCLOSURE RULES

All analyses will be at the aggregate level. All authorized researchers agree that they will under no circumstances describe or present individual cases publically; list, describe or identify tract or tracts by number, by name, or by descriptive information; create maps with any features that allow tracts to be identified; and summarize statistics that have cell sizes under 11 observations.

Steps to return or destroy the original and subsequently created data sets:

At the conclusion of the project, the data and work areas on the hard drive will be erased with ‘secure erase’ software. The CD-ROM stored in Lisa Neidert’s office will be destroyed at the conclusion of the project (or can be returned if Georgia DPH would prefer to have it returned intact).

<table>
<thead>
<tr>
<th>PLEASE ACKNOWLEDGE EACH BELOW by checking the appropriate box:</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>Is IRB Approval required? If yes, please send a copy.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>We agree to adhere to the policies and procedures set forth in Part A: Protected Health Information and in Part B: Data Use Policy.</td>
<td>X</td>
<td></td>
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<tr>
<td>We acknowledge that these data cannot be used outside the scope presented within this document.</td>
<td>X</td>
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</table>
We agree to serve as coauthor with employees from DPH MCH Program in all literary works and presentations using the requested data

Any publications/presentations will be sent to DPH for review prior to publication:

This signed form is not perpetual and a new form must be signed for each request or use of data unless otherwise approved in writing.

Signature (electronic acceptable)  Date

Print Name

Title

Organization

FOR DPH INTERNAL USE
Description of data release

Email form to ohip@dhr.state.ga.us or fax to (404) 656-9880