

**MEMORANDUM OF AGREEMENT
BETWEEN**

**SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL
CONTROL
AND**

**STATE BUDGET AND CONTROL BOARD
OFFICE OF RESEARCH AND STATISTICS**

**TO LINK MATERNAL AND CHILD HEALTH DATA FILES FOR PUBLIC HEALTH
RESEARCH, EVALUATION AND SURVEILLANCE**

This Memorandum of Agreement (MOA) is entered into as of the first day of June 2004, by and between the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina, 29201, (hereinafter referred to as DHEC), and the State Budget and Control Board, Office of Research and Statistics, 1919 Blanding Street, Columbia, SC 29201 (hereinafter referred to as ORS).

RECITALS

WHEREAS, DHEC and ORS have a valid Memorandum of Agreement to establish a mechanism for linkage and analysis of data files and a Memorandum of Agreement to link program information from the DHEC Division of Children with Special Health Care Needs, this present Memorandum of Agreement will provide additional DHEC, Bureau of Maternal and Child Health information for linkage and analysis.

WHEREAS, DHEC and ORS recognize the advantages of linked and de-identified state agency data to:

- Conduct research and evaluation in support of policy decision-making and program monitoring; and
- Assist in public health surveillance.

WHEREAS, individually identifiable data under this Agreement are governed by strict federal and state rules that restrict disclosure. The patient and program information provided by DHEC under this Agreement may be released only with the written permission of the program directors accountable for the data and in compliance with established DHEC procedures for protecting confidentiality.

NOW THEREFORE, by entering into this Agreement, the parties intend to cooperate in creating linked, de-identified data files that will be used for public health and health care research, program evaluation, and surveillance. Data files to be analyzed will be dependent on the specific project at hand. Projects must be approved on a case-by-case basis by the appropriate entities included in this Agreement before an analysis can begin. The data will only be used for public health and health care research, evaluation or surveillance purposes and will not be used

to determine eligibility or to make any other determinations affecting an individual. It will include no follow-up or corrective action directed to specific patients or toward specific institutional or individual providers.

ARTICLE I AGREEMENT PERIOD

This Agreement shall take effect as of June 1, 2004, and continue through June 30, 2006, unless terminated by either party in accordance with the terms of Article V, Termination.

ARTICLE II PURPOSE

The purpose of this MOA is to establish the parameters for the linking and analysis of maternal and child health data files with other state agency and hospital utilization data sets for public health and health care research, evaluation and surveillance purposes.

ARTICLE III ROLES AND RESPONSIBILITIES

- A. SC DHEC will be responsible for:
1. Providing client specific data from the following program information systems:
 - a. Maternal Health
 - b. Child Health
 - b. WIC
 - c. Family Planning
 - d. Childhood Lead Poisoning Prevention
 - e. Oral Health
 - f. Laboratory
 - g. Perinatal Regional Transportation
 - h. High Risk Perinatal and Patient Automated Tracking System or Client Automated Record and Encounter System in accordance with program approvals and the guidelines established by the DHEC, Bureau of Maternal and Child Health Data Committee as stated in Article VI.D.
 2. Providing ORS with documentation and code structure for each data set.
 3. Ensuring that DHEC and DHEC funding agencies have the authority to audit, confirm and test that adequate procedural controls are in place to protect the confidentiality and use of data shared under this agreement.

4. Geocoding DHEC Public Health Information and Statistics (PHSIS) all linked address data using Census geography levels, adding these variables to the linked data sets, and returning the geocoded datasets to ORS for custodianship.
- B. ORS will be responsible for:
1. Establishing and maintaining procedures and controls so that information identifying DHEC clients cannot be obtained by any person or entity except as provided under state statutes or regulations. These procedures shall include automated data processing procedures to control access to files and ensuring the control of confidential disposal of all data stored in any form or medium.
 2. Holding in strictest confidence the identity of all DHEC clients. ORS shall use personal identifiers solely for the purpose of linking DHEC client information with information from other participating agencies and health care providers. ORS will add DHEC identifiers, stripped of statistical data, to its master client index file for purposes of creating a unique tracking number that will be attached to client statistics data stripped of identifiers. ORS will maintain client identifiers in its separate password-protected master client index file so that identifiers cannot be linked to the de-identified statistical data sets.
 3. Performing the link between the DHEC datasets and other state agency and health care utilization data sets to create de-identified data sets for public health and health care research, evaluation and surveillance.
 4. As custodian of the linked files, ORS shall coordinate all requests for access to the linked data files. Only requests for linked data are considered under this Memorandum of Agreement: requests for specific un-linked program data must be referred to the specific program. All researchers or requesting entities must comply with the conditions outlined in Article VI.F.
 - a. ORS will notify the MCH Epidemiologist of all requests to utilize linked data files. Requests must be made in writing and must include items specified in VI.F.
 - b. ORS will only release requested data if all entities involved have approved the data request. The approval process is outlined in Section VI.
 - c. ORS will not release to any program or group a copy of a data set containing case-by-case listings of vital statistics data (linked or unlinked) without specific approval by the Office of Public Health Statistics and Information Services on a project-by-project basis.

ARTICLE IV AMENDMENT

No amendment or modification of this Agreement shall be valid unless it shall be in writing and signed by all parties hereto. Unless amended in writing, the specifics as stated in this Agreement regarding data file maintenance, access, confidentiality, and uses shall remain in effect as long as the linked data set or a derivative exists.

ARTICLE V TERMINATION

TERMINATION CLAUSES:

1. Subject to the provisions contained below, this Contract may be terminated by either party providing written notice of that intent to the Contractor 30-days in advance.
2. Funds for this Contract are payable from State and/or Federal and/or other appropriations. In the event sufficient appropriations are not made to pay the charges under this Contract, it shall terminate without any further obligation by DHEC.
3. DHEC may terminate this Contract for cause, default or negligence on the part of the Contractor at any time without thirty days advance written notice.

ARTICLE VI CONFIDENTIALITY TERMS

A. MATERNAL AND CHILD HEALTH CONFIDENTIALITY

Confidentiality and anonymity of clients and providers shall be preserved by observing the following conditions:

1. Maternal and Child Health information is subject to state and federal safeguards of confidentiality. After completing the linkage of the data files, information that could be used to identify individual patients, specifically name, address information, e-mail address, social security number, patient identification number, account number, certificate number, facial photography, and telephone numbers will be stripped from the research files. After completing the linkage of the data files, information that could be used to assist in the evaluation of the health and safety of patients such as license number, vehicle identification numbers, device identification numbers and Medicaid record number will be stripped from the linked file and stored in a separate location for use with approved research projects. To identify each record, a unique identification number will be

generated by ORS. ORS will retain, but not share, the ability to individually identify each record so that additional data files may be linked. However, it is the intent of this Agreement that no data which can be re-identified shall be released from ORS once it has been linked to data from another party or source. The intent of the Agreement is to create a continuing de-identified pool of unique cases which can be used for research, evaluation and public health surveillance, not to allow any of the parties to individually identify data from another party or source. No GIS analysis that identifies street addresses or individuals will be released using Maternal and Child Health data.

2. Upon completion of the linkages, the original data files will be returned to DHEC.
3. A copy of the de-identified, linked maternal and child health and Vital Records research data files (including only the data supplied by DHEC) will be sent to DHEC Public Health Statistics and Information Services.
4. The Maternal and Child Health Data Committee will include the Director of the DHEC Bureau of Maternal and Child Health or designee, the DHEC MCH Epidemiologist, the Director of the DHEC Office of Public Health Statistics and Information Services or designee, the Director of the Office of Research and Statistics or designee, and the Director of the Bureau of Program Support, Department of Health and Human Services or designee. The Maternal and Child Health Data Committee will be responsible for reviewing all requests for the use of linked maternal and child health data.
5. The use of each specific program data file must be approved by the MCH Bureau Director and the designated program authority as follows:
 - a. Maternal Health
 - b. Child Health
 - c. Family Planning
 - d. Childhood Lead Poisoning Prevention
 - e. High Risk Perinatal program data - the Director of Women's and Children's Services
 - f. WIC program data – the Director of WIC
 - g. Laboratory data – the Director of the Bureau of Laboratories;
Perinatal Regional Transportation – the Director of Perinatal Systems
 - h. Oral Health - Director of Oral Health
 - i. Vital Records – the Director of the Office of Public Health Statistics and Information Services.

Requests for data covered under this MOA that have been linked with other state agencies or health care providers data must also receive approval through the appropriate processes as established by ORS.

6. Requests for use of data generated under this Agreement will at a minimum provide the following information:
- a. Principal research investigator
 - 1) Name
 - 2) Position/job title
 - 3) Organization/firm name and address
 - 4) Telephone and FAX number
 - 5) Alternative contact person and phone number

 - b. Purpose/reason for the data request
 - 1) Reason(s) why data is needed
 - 2) Study objectives and, where applicable, hypothesis to be tested.
 - 3) How are the results to be used (Indicate if the proposed analysis will be used for legal, administrative or other actions which may directly affect particular individuals or health care providers or professionals.)?
 - 4) Previous data requests (Y/N)
 - 5) Explain the benefits of the study

 - c. Description of data and/or services desired
 - 1) Specific data set requested
 - 2) Vital event(s) involved
 - 3) Type of data
 - 4) Time interval
 - 5) Geographic Parameters
 - 6) Classification of data (list of specific data elements or groups)
 - 7) Desired electronic medium (e.g., 9-track tape, 3480 tape cartridge, 3.5 or 5.25 diskettes) and file format (e.g. ASCII, EBCDIC, d-Base)

 - d. Manipulation of Data
 - 1) Briefly describe the analysis to be performed (specific methodologies and statistical, econometric, biostatistical and/or other mathematical manipulations and/or models).
 - 2) Briefly describe geographic level of analysis and use of any Geographic Information System (GIS) applications.

 - e. Presentation and dissemination
 - 1) Describe how the data and/or results will be displayed
 - 2) Describe how the data and/or results will be disseminated (Detail in what form and to whom the results will be released or disseminated).
 - 3) Describe any intended use and level of geographic display for presentation and/or dissemination.

- f. Length of study/project
- g. Storage
 - 1) Describe what methods will be employed to physically secure the data.
 - 2) Describe the safeguards which will be employed to protect against unauthorized access and use.
 - 3) Describe the procedures for protecting the confidentiality of patients and health care providers and/or professionals.
 - 4) Describe the plans for disposal of the restricted/confidential data elements upon completion of the project. Within 30 days of completion of the approved project, all original data sets will be returned to ORS. Any copies of the data sets made by the researcher will be destroyed with written notification to ORS that all copies have been destroyed.
 - 5) List the name and title of all individuals with access to the data (including employees, consultants, contractors, subcontractors, technical advisors and any other individuals who will have access to the data).
- h. Signed confidentiality contract with ORS.
 - 1) Such requests shall not be approved by DHEC or ORS if the data requested are such that an individual researcher could reconstruct identifiable data.
 - 2) If the request for use of this data is approved, the requestor will be bound under a MOA drafted to specify the use, publication requirements, and confidentiality requirements for the use of said data and must be signed by an authorized representative of DHEC and ORS. SCDHEC and ORS may require other specifications before the researcher receives approval.
- 7. DHEC, General Accounting Office, or its designee, has the right to audit and confirm and test that adequate procedures and controls are in place to protect the data shared under this Agreement.
- 8. DHEC and ORS shall observe the following requirements that apply to any formal presentation of any findings, conclusions or opinions resulting from use of the data. ("Formal presentation" includes, but is not limited to papers, articles, professional publications, speeches, lectures, and testimony.):
 - a. DHEC and/or ORS shall be notified prior to any formal presentation, and shall be afforded a reasonable period of time (a minimum of 15 working

days and not to exceed 30 days) to review the findings, conclusions or opinions prior to any such formal presentation.

- b. DHEC and/or ORS shall have the right to delay or prohibit any formal presentation if, in its opinion, such action is necessary for the agency to remain in compliance with federal or state statutes or regulations, or to fulfill obligations under the terms of any Agreement between DHEC and ORS. In the event such action is taken, DHEC and/or ORS shall provide clear references and explanations to the presenter.
 - c. DHEC and/or ORS, require the inclusion of a disclaimer that the findings, conclusions or opinions contained in any formal presentation are those of the author/presenter and do not necessarily reflect the findings, conclusions or opinions of DHEC and/or ORS.
 - d. DHEC and ORS shall have a royalty-free, nonexclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use for governmental purposes, any copyrightable material developed in the course of activities that are the subject of this Agreement.
9. DHEC (the designated approving persons) and ORS (the designated approving persons) will be notified when a manuscript has been accepted for publication. The notification shall include the name of the journal or publication and include a copy of the final version of the manuscript accepted for publication.
 10. DHEC and ORS do not assume responsibility for any data calculations, data manipulations, interpretations, or conclusions that users may make from the data. Any publications utilizing the data will acknowledge these two agencies as the source of the data. Such an acknowledgment must make it clear that these agencies are responsible as the source of data only, and not for any content of publications and/or dissemination of study results.
 11. The de-identified linked data set prepared in response to an individual request cannot be linked to any other data set, including those within their respective agencies, without prior written approval of DHEC and ORS. Information specified in Article IV.F shall be provided to the aforementioned agencies in order to receive consideration for further linkages. The designated approving persons for DHEC (all approvals required) are specified in Article VI.E. The designated approving persons for ORS are the Chief of Health and Demographics or designee for use of non-restricted variables, and the South Carolina Data Oversight Council for restricted variables.

B. AGENCY CONFIDENTIALITY TERM

1. The Contractor agrees to abide by DHEC's policy of confidentiality, which states that all information as to personal facts and circumstances given or made available to employees/volunteers and/or contractors of DHEC in administration of programs shall be held confidential and shall not be divulged without consent of the programs and services and individual(s) to which it pertains. Confidential agency information and action shall not be divulged.

Certain information received by DHEC may not be released pursuant to the Family Privacy Protection Act. Information that is otherwise available to the public under the Freedom of Information Act may be released in accordance with State law. Should information identify a DHEC client or employee, it may not be released outside of the agency except upon receipt of a properly completed authorization signed by the individual or his/her parent or guardian. If information is released pursuant to the receipt of a properly completed authorization, documentation of the release must be maintained. A copy of the authorization must be included in this documentation.

Protected Health Information generally cannot be released except pursuant to a proper authorization by the client or his/her parent or guardian, or pursuant to a specific exception under the Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164). DHEC may conduct routine audits of health records to ensure compliance with this procedure.

Any unauthorized disclosure of confidential information may result in termination of this contractual relationship with DHEC and may be grounds for fines, penalties, imprisonment, civil suit, or debarment from doing business with the State.

The Contracting Party shall immediately notify the District Medical Director and DHEC HIPAA Privacy Officer of any possible breach of privacy or security of DHEC client's protected health information under the HIPAA Privacy Rule or applicable state law that occurs in the course of performing this Agreement.

The Contracting Party and employees/agents of the Contracting Party will be required to sign DHEC's Confidentiality Agreement (DHEC form #0321), a copy of which is attached hereto. Alternatively, if the Contracting Party desires to rely upon an existing Confidentiality Agreement signed by its employees/agents, a copy of the Confidentiality Agreement must first be provided to the DHEC Contract Officer for evaluation, and the Contracting Party must provide verification that all employee/agents obtaining access to DHEC confidential information in the course of performing this agreement have executed the Confidentiality Agreement.

2. Prior to participating in any DHEC clinical activity or rendering any service to DHEC under this Agreement, the Contracting Party and employee/agents of the Contracting Party will be educated and trained regarding the Health Insurance Portability and Accountability Act of 1996 and related Regulations pertaining to the privacy and security of protected health information (the HIPAA Privacy Rule.) The Contracting Party will provide documentation of successful completion of this training to the Contract Officer prior to initiating performance of this Agreement. If this training has not been conducted, or documentation of training has not been provided, the Contracting Party and its employees/agents will be required to view DHEC's HIPAA training video(s) and receive necessary instruction on the DHEC forms referenced in the training prior to initiating performance of this Agreement.

ARTICLE VII LIABILITY

Neither party shall be liable for any claims, demands, expenses, liabilities and losses (including reasonable attorney's fees) which may arise out of any acts or failures to act by the other party, its employees or agents, in connection with the performance of services pursuant to this MOA.

ARTICLE VIII NON-DISCRIMINATION

No person shall be excluded from participation in, be denied benefits of, or be subjected to discrimination in relation to any activities carried out under this MOA on the grounds of race, handicap, color, sex, religion, age, health status or national origin.

ARTICLE IX GOVERNING LAW

The agreement and any dispute, claim, or controversy related to the agreement shall, in all respects, be interpreted, construed, enforced and covered by and under the laws of the state of South Carolina. All disputes, claims or controversies relating to the agreement shall be resolved in accordance with the South Carolina Procurement Code, Section 11-35-10, et. Seg., and the contractor agrees to subject himself to the jurisdiction and process of the courts of the State of South Carolina

ARTICLE X FINANCIAL RESPONSIBILITY

Under this agreement each party shall bear and be responsible solely for its own costs and expenses necessary to comply with this MOA.

IN WITNESS WHEREOF, DHEC and ORS, have executed this Agreement as of the first day of June 2004.

STATE BUDGET AND CONTROL BOARD, OFFICE OF RESEARCH AND STATISTICS (ORS)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL (DHEC)

**BY: _____
Walter P. Bailey, Chief
Health and Demographics**

**BY: _____
Sara Balcerek, Director
Bureau of Maternal and Child Health**

DATE: _____

DATE: _____

HEALTH SERVICES ADMINISTRATION

**BY: _____
Benjamin R. Lee, Director**

DATE: _____

This Contract is not legal and binding until signed by the Chief of Staff

**BY: _____
Doug Calvert, Chief of Staff**

DATE: _____



DHEC Confidentiality Agreement

I understand that the South Carolina Department of Health and Environmental Control (DHEC) has a legal and ethical responsibility to maintain confidentiality of information as to personal facts and circumstances of DHEC clients, employees, or other citizens given or made available to DHEC in administration of the agency's programs and services.

DHEC's Confidentiality Policy states that Information about personal facts and circumstances of DHEC employees and clients will be kept confidential and will not be disclosed without the individual's written authorization, except as required by law. Protected Health Information that identifies an individual generally cannot be released unless properly authorized by the client or his/her legal representative, or pursuant to a specific exception under the Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164). The Family Privacy Protection Act may place additional limitations on disclosure of personal information.

Information that is made available to the public under the Freedom of Information Act must be disclosed in accordance with State law. However, the Freedom of Information Act protects information of a personal nature such that public disclosure would constitute an unreasonable invasion of privacy. The types of information that generally must be kept confidential include, but are not limited to: protected personal information of job applicants or DHEC employees, vital records information, social security numbers, and health information that identifies individuals.

I understand that during the course of my employment, volunteer services, or contract performance with DHEC, I may see or hear confidential information and/or protected health information.

By signing this agreement, I understand and agree that I will not disclose confidential information or protected health information unless the disclosure complies with DHEC policies and is required to perform my responsibilities. I will not access or view any information other than what is required to do my job. If I have any questions about whether I need access to certain information, or whether certain information should be disclosed, I will immediately ask my supervisor for clarification.

I will not discuss any confidential information or protected health information obtained in the course of my relationship with DHEC with any person or in any location outside of my area of responsibility in DHEC, except as otherwise required or permitted by law. I will not make any unauthorized copy or disclosure of this information, or remove or transfer this information to any unauthorized location.

I agree that my obligations under this Agreement regarding confidential and protected health information will continue after termination of my employment/volunteer assignment/contract affiliation with DHEC.

I understand that violation of this Agreement may result in termination of my volunteer, contractual and/or work relationship with DHEC and may be grounds for disciplinary action, fines, penalties, imprisonment or civil suit to be brought against me.

I have read the above Agreement and agree to comply with all its terms.

Signature: _____

Date: _____

Witness: _____

Date: _____

Work Location: _____