1. Policy Statement

This policy covers the standards for privacy of individually identifiable health information. This policy applies to

a. Rutgers University employees who are employed within covered entities that are a part of the Rutgers Biomedical and Health Sciences (“RBHS”), RBHS researchers as well as any independent contractors engaged by RBHS; and

b. Any Rutgers University employees who are employed by a Rutgers school, unit or department that is a covered entity and that bills federal and/or state programs for the provision of healthcare-related goods or services, any researchers in the school, unit or department as well as any independent contractors engaged by the affected school, unit or department.

   For purposes of this policy, the groups and entities described in (a) and (b) above shall be referred to as “RBHS Covered Entity” or “RBHS Covered Entities.”

2. Reason for Policy

To establish guidelines for assuring that all RBHS Covered Entities handle or create individually identifiable health information understand the standards that have been established under the law.

3. Who Should Read This Policy

This policy shall apply to health information that is generated during provisions of health care to patients in certain patient care units, patient care centers or faculty practices as well as Human Subjects research including:
a. Covered entities and their employees who are a part of Rutgers Biomedical and Health Sciences ("RBHS"), RBHS researchers as well as any independent contractors engaged by RBHS; and
b. Any Rutgers University covered entities and their employees who bill federal and/or state programs for the provision of healthcare-related goods and services as well as any independent contractors engaged by the affected school, unit or department.
   i. For purposes of this policy, the groups and entities described in (a) and (b) above shall be referred to as “RBHS Covered Entity” or “RBHS Covered Entities.”
c. Business Associates of the RBHS Covered Entities.
d. Other University departments that assist the RBHS Covered Entities in certain activities including, but not limited to, the Office of Information Technology and the Office of the Senior Vice President and General Counsel.

4. Related Documents
   B. 45 CFR, 164.514(e), Code of Federal Regulations, Title 45, Part 164, Subpart E, Security and Privacy, Privacy of Individually Identifiable Health Information
   D. Records Management and Record Retention Schedules
   E. Accounting of Disclosures of Health Information
   F. Disclosures of Personally Identifiable Health Information to Business Associates
   G. Protected Health Information Breach Notification Policy

5. Contacts
   RBHS Director of Privacy: 800-215-9664
   RBHS Office of Ethics, Compliance and Corporate Integrity: 973-972-8093

6. The Policy

100.1.9 STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

RHBS Covered Entities will implement and maintain a Privacy Program to assure compliance with state and federal laws and RBHS and Rutgers policies protecting the confidentiality of individually identifiable health information of its patients and/or Human Subjects. The RBHS Privacy Program will complement the Rutgers and RBHS Information Security policies.

All RBHS Covered Entity’s employees, students, and individuals working on behalf of the RBHS Covered Entity in any capacity (including Board members, medical staff, business associates, independent contractors, and volunteers) will conduct themselves and their activities in a manner so as to protect the confidentiality of patients’ individually identifiable health information as required by state and federal laws and in conformance with University policies.

A. Requirements:
   1. The Privacy Program for the RBHS Covered Entities will consist of the following elements:
      a. RBHS Office of Ethics, Compliance and Corporate Integrity, School, Department or Unit Privacy Officers/Privacy Liaisons
         i. The Chief Healthcare Compliance Officer, and the RBHS Director of Privacy, will oversee the development, implementation and maintenance of the Privacy Program for the
ii. If an RBHS Covered Entity has a Compliance Officer, the Compliance Officer will also serve as the School or Unit Privacy Liaison. If the RBHS Covered Entity does not have a Compliance Officer, the RBHS Covered Entity will nominate a Privacy Officer. The Privacy Officer/Privacy Liaison will assist the RBHS Director of Privacy in implementing the Privacy Program and University-wide policies and procedures within the schools/units, and overseeing the development, implementation and maintenance of school/unit or departmental privacy policies and procedures as appropriate.

iii. Rutgers Institutional Review Boards (IRBs), will assure that informed consents include appropriate authorizations for disclosure or that authorization has been appropriately waived.

b. School and Healthcare Unit Custodian of Medical Records

i. Presidents/CEOs and Deans of the RBHS Covered Entities maintaining Protected Health Information (PHI) will appoint a Custodian of Medical Records.

ii. It will be the responsibility of the Custodian of Medical Records to assure that processes are in place at their Healthcare Unit or School, and subordinate work units, to implement and monitor compliance with the elements detailed in Section V.A.1.c., below.

c. The Chief Healthcare Compliance Officer, through the RBHS Director of Privacy, and with the assistance of appropriate Custodian of Medical Records and each Privacy Officer/Privacy Liaison, will direct that within each RBHS Covered Entity the following elements are developed, implemented and maintained in conformance with state and federal requirements, and are reflected in policies and procedures accordingly:

i. Providing notice to patients of the RBHS Covered Entity’s privacy practices for Protected Health Information (PHI);

ii. Protecting the confidentiality of uses and disclosures of PHI, including requiring appropriate authorizations, and/or an opportunity to agree or object when mandated by law for uses and disclosures of PHI;

iii. Implementing appropriate and reasonable administrative, technical, and physical safeguards to protect the privacy of PHI from unauthorized use or disclosure;
iv. Assuring that a written process is in place that allows individuals to restrict uses and disclosures of their health information. The RBHS Covered Entity, however, is not required to agree to such requests.

v. Assuring that patients can receive communications of their health information by alternate means or alternate locations, if requested.

vi. Implementing a written process for maintaining and providing an accounting of the RBHS Covered Entity’s uses and disclosures of PHI to requesting individuals to whom the information pertains;

vii. Assuring that a written process is in place that allows individuals to access, inspect and/or obtain a copy their health information;

viii. Assuring that a process is in place that allows individuals to request that a unit amend their health information. The RBHS Covered Entity, however, may deny requests under specified circumstances;

ix. The Privacy Officer/Privacy Liaisons will be the designated contact person(s) for individuals seeking further information or clarification to the RBHS Covered Entity’s health information policies, and privacy and patient rights requirements covered under the notice. The RBHS Director of Privacy will be designated to receive complaints concerning the RBHS Covered Entities compliance with health information privacy and patient rights requirements.

d. All existing or new unit or departmental policies and procedures addressing any of the items in this policy, or that concern the use or disclosure of PHI, and all consent/authorization forms for the disclosure of PHI, must be presented to the RBHS Director of Privacy, through and in consultation with the Privacy Officer/Privacy Liaison for review to assure compliance with University-wide policies, RBHS-specific policies as well as state and federal requirements.

e. The Privacy Officer/Privacy Liaison will communicate periodically, with the RBHS Director of Privacy and the Presidents/CEOs and Deans of the RBHS Covered Entities on the status of all policies and procedures concerning PHI, the Privacy Program, including its implementation, training, any recommended changes or amendments. The Privacy Officer/Privacy Liaison will immediately notify the RBHS Director of Privacy of any complaints or issues of non-compliance with Rutgers or RBHS Compliance and Privacy policies.
f. RBHS Covered Entities will promptly revise policies and procedures related to the Privacy Program as discussed above as necessary and appropriate to comply with changes in the law. All policies and procedures will be reviewed periodically by the RBHS Director of Privacy, along with the Privacy Officers/Privacy Liaisons to assure compliance with the laws, as well as for operational effectiveness. If the changes in the law also materially affect privacy practices stated in the RBHS Covered Entity’s notice to patients regarding privacy practices, the notice must also be changed in a timely manner.

g. All notices to patients concerning the RBHS Covered Entity’s privacy practices must state the RBHS Covered Entity reserves the right to make changes in its privacy practices at any time.

2. Education and Training

a. The RBHS Director of Privacy will recommend training to refresh the RBHS Covered Entities’ workforce regarding the Privacy Program, policies and procedures and the regulatory requirements, as appropriate.

b. The RBHS Office of Ethics, Compliance and Corporate Integrity will take necessary efforts to offer new members of the RBHS Covered Entity’s workforce privacy training within 30 days of hire.

c. Privacy Officers/Privacy Liaisons will coordinate additional training of the workforce whose functions are affected by a material change in the policies and procedures within a reasonable period of time after the change becomes effective.

d. Training provided will be appropriately documented and the documentation will be maintained by the Privacy Officer/Privacy Liaisons for a minimum of six (6) years or as specified by the Records Management Policy and the attendant Record Retention Schedules, whichever is longer.

3. Non-retaliation for exercise of Patient Rights

Rutgers Biomedical and Health Sciences will maintain in the RBHS Code of Conduct and other applicable policies and procedures that state intimidating, threatening, coercing, discriminating or taking other retaliatory action against the following is prohibited as outlined in the RBHS Covered Entities’ Notices of Privacy Practices for Protected Health Information:

a. Patients for exercising any right established by HIPAA privacy guidelines, 45 CFR 164, subpart E;

b. Individuals and others for filing a complaint with the Secretary of Health and Human Services under 45 CFR 160, subpart C;
c. Individuals and others for testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under Part C of Title XI; or

d. Individuals or others for opposing any act or practice made unlawful by 45 CFR 164, subpart E, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of the opposition is reasonable and does not involve a disclosure of PHI in violation of 45 CFR 164, subpart E.

B. Responsibilities:

1. The Chief Healthcare Compliance Officer or designee shall be responsible for communicating and enforcing the above policy as it relates to all employees University-wide.

2. The Medical Directors, President/CEOs of the RBHS Covered Entities and Research Deans shall be responsible for communicating and enforcing the above policy as it relates to persons involved in patient and human subject contact.

3. The Executive Director, University, Procurement Services or his or her designee shall be responsible for communicating and enforcing the above policy as it relates to vendors, independent contractors, business associates, etc.

4. RBHS Covered Entities may not require individuals to waive their rights to file a complaint with the Secretary of Health and Human Services or any other right under CFR 164, subpart E, including 164.500 through 164.530, as a condition of the provision of treatment, payment, enrollment in a health plan or eligibility for benefits.

5. Monitoring and Evaluation

a. The RBHS Compliance Committee is the governing body for the evaluation and monitoring of the RBHS Privacy Program and will review compliance issues as appropriate.

b. The IRBs and the University’s Research Compliance Officer will monitor compliance with requirements for research related disclosures.

c. The RBHS Director of Privacy will periodically request external or internal audits to be conducted to ensure compliance with this policy.

d. The RBHS Director of Privacy is responsible for investigating and reporting on allegations of non-compliance with the privacy policies applicable to the RBHS Covered Entities.

e. Privacy Officers/Privacy Liaisons, under the direction of the RBHS Director of Privacy, may be asked to conduct investigations of non-compliance with the privacy policies applicable to the RBHS Covered Entities.
6. Sanctions for Non-Compliance

a. The RBHS Covered Entities will apply appropriate sanctions, against any member of the workforce who fails to comply with the University’s privacy policies and procedures and the privacy policies and procedures applicable to the RBHS Covered Entities.

b. The Deans and President/CEOs of RBHS Covered Entities, with the assistance of University Human Resources, will enforce the sanctions appropriately and consistently.

c. The RBHS Covered Entities will document all sanctions that are applied.

7. Documentation

Documentation evidencing implementation of the Privacy Program applicable to RBHS Covered Entities, including complaints, training, sanctions, auditing, etc., will be maintained for a minimum of six (6) years or the time period specified by the Records Management Policy and attendant Record Retention Schedules, whichever is longer.