COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY ON RESEARCH AND THE HIPAA PRIVACY RULE

I. SCOPE:

This Policy clarifies the implementation of the HIPAA Privacy rule by Columbia University ("Columbia") and that the Institutional Review Board (IRB) will assume the responsibilities of the Privacy Board (PB).

II. EFFECTIVE DATE: April 28, 2008

III. INTRODUCTION

All activities constituting human subjects research must be reviewed by an IRB prior to initiation of the research in accordance with regulations of the Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR 56) (collectively, the "Regulations") unless such research activities are exempt from review pursuant to 45 CFR 46.101(b) and 21 CFR 56.104 ("Exempt Research").

It is Columbia's policy that the requirements of 45 CFR 46 apply to all human subjects research conducted by Columbia faculty, staff, and students, and other research as articulated in the Columbia IRB Standard Operating Procedures. Per Columbia policy, research that may constitute Exempt Research per 45 CFR 46 must be submitted to the IRB for a determination that such research should in fact be considered exempt.

In addition, the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), effective April 14, 2003, governs the use of data involving protected health information by investigators who are part of a covered entity as defined by HIPAA, or who are clinicians that are members of an Organized Health Care Arrangement (OHCA) with the given institution. The Privacy Rule also governs disclosures of data to individuals, whether affiliated with the covered entity or not, who propose to use such data for research purposes. Columbia University is a covered entity per HIPAA criteria.

This policy supplements, but does not supplant, other policies and procedures governing IRB review of research protocols. The Columbia IRB shall review research protocols in accordance with all applicable institutional policies and procedures and shall serve as the Privacy Board to fulfill responsibilities required by the Privacy Rule.

HIPAA policies apply to all individuals, including Officers of Instruction, Officers of Research, Officers of the Libraries, students and members of research staff, who may be involved in research at the University, to all Research conducted by such individuals, whether funded or not, federally or otherwise, and to all proposals for human subjects research at Columbia.

The Columbia HIPAA policies, including HIPAA Research policies, require that human subjects research using protected health information must meet one of the following criteria:

- a HIPAA Authorization will be signed by the study participant;
- a HIPAA Waiver of authorization will be obtained from the IRB;
- the activity qualifies as preparatory for research;
- the researcher uses information solely on decedents;
- the information is completely de-identified and no longer governed by HIPAA;
- the information is compiled into a "limited data set" and a data use agreement is executed.

IV. DEFINITIONS

"Authorization": an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization.

"Disclose/disclosure": the release or transfer of information to, or the provision of access to information by, a person or entity outside of the entity holding the information.

"Exempt research": research that involves human subjects but is not subject to the requirements of 45 CFR 46 or 21 CFR 56.104. Review by the IRB of projects described in 45 CFR 46.101(b) is required per institutional policy.

"Informed consent": the process by which individuals are given information necessary to decide whether or not to participate in a research study and provided the opportunity to voluntarily agree to such participation without coercion or undue influence.

"Limited data set": protected health information from which direct identifiers have been removed that may be used and disclosed for research purposes pursuant to a data use agreement.

"Organized Health Care Arrangement ("OHCA"): a clinically integrated care setting, such as a hospital or clinic, where patients receive treatment from more than one provider. CUMC has established an OHCA with NewYork Presbyterian Hospital, Weill Cornell Medical Center, and Harlem Hospital, the latter being limited to research conducted by Columbia faculty.

"Human Subject (Participant)": For purposes of IRB review, a living individual about whom an investigator conducting research obtains data through intervention or interaction, or obtains private identifiable information (45 CFR 46), or an individual who participates in research, either as the recipient of a test article or as a control (21 CFR 56]. For purposes of the HIPAA Privacy Rule, decedents are also included

"Privacy Rule": Standards for Privacy of Individually Identifiable Health Information, promulgated by the U.S. Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and codified at part 160 and part 164, subpart E, of Title 45 of the U.S. CFR (as amended from time to time).

"Protected Health Information (PHI)": information transmitted or maintained in any form (i.e., by electronic means, on paper, or through oral communication) that: (1) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for health care; and (2) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. As a general matter, protected health information includes any information maintained by or on behalf of, or created about or received from patients of, Columbia University that includes any of identifiers of an individual or an individual's relatives, household members, or employer(s).

"Sponsor": third-party organization that provides funding for the conduct of a research protocol (i.e., unaffiliated with Columbia).

"Research": a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research purposes

"Third Party Investigator": an investigator unaffiliated with Columbia.

"Use": the sharing, employment, application, examination, or analysis of protected health information within an entity that maintains such information.

"Workforce": employees, volunteers, trainees, and other persons whose conduct in the performance of work is done under the auspices of Columbia.

V. COMPLIANCE WITH LAWS, REGULATIONS AND POLICIES

Columbia will ensure compliance with applicable laws and regulations that govern use or disclosure of health information for research by Columbia affiliated investigators and the release of such information to their Sponsors or other non Columbia University organizations. All research using data maintained by or on behalf of, or created about or received from patients of, or research subjects involved in studies conducted by, Columbia, shall be conducted in accordance with applicable requirements of federal health privacy standards promulgated by HHS pursuant to the HIPAA Privacy Rule and applicable state and federal laws or regulations.

VI. IRB PROCEDURES FOR REVIEW AND APPROVAL OF HIPAA FORMS

As provided in the policies of Columbia, the IRB shall evaluate research proposals involving the use or disclosure of protected health information maintained by or on behalf of, or created or received from patients of, or research subjects involved in studies conducted by, Columbia University, in accord with applicable standards of the Privacy Rule and in compliance with the Human Research Protection Program (HRPP), collectively, as described in this policy. The HRPP is charged with the responsibility of ensuring that all human subjects' research conducted by Columbia faculty, employees, and staff is conducted ethically and in a manner that promotes the protection of human subjects in research.

All HIPAA forms requiring completion will be reviewed and approved as part of the protocol approval process. The Columbia Privacy Officer is an agent of the IRB charged with the responsibility for ensuring review of all HIPAA research privacy requirements within each protocol, including the

HIPAA research forms included within a protocol. Throughout this policy and affiliated procedures, references to the Privacy Officer should be interpreted as "the Privacy Officer and his/her designee".

Investigators proposing research protocols and/or review of patient information preparatory to research are required to submit the appropriate HIPAA form(s) in RASCAL. Depending upon the proposed procedures, submission of a protocol for IRB review may be required at the same time. If a protocol is submitted for preparatory to research procedures without HIPAA forms, the Investigator will be directed to complete HIPAA related research forms.

The forms and related procedures (described in detail in a separate document) to comply with the HIPAA research requirements include:

Nature of Research or Protocol Component	**Applicable Form**	**Procedure**
Clinical Research Authorization (sponsored and non-sponsored)	Form A	Procedure#1
Application for a Waiver of Authorization	Form B	Procedure#2
Request for Recruitment Waiver of Authorization	Form C	Procedure#3
Investigator's Certification for Review Preparatory to Research	Form D	Procedure#4
Investigator Certification for Research with Decedent Information	Form E	Procedure#5
Data Use Agreement for Disclosure of Limited Data Set	Form F	Procedure#6
Investigator Certification for Research with De-Identified Data	Form G	Procedure#7

The Privacy Officer will respond to any HIPAA related issues or concerns identified during the review, approval, modification or ongoing monitoring of a research protocol.

- **Review of "Not Human Subjects Research" Activities that include Protected Health Information**

  The Privacy Rule applies to Columbia's use or disclosure of protected health information, including those for investigative purposes that involve data about patients for whom the federal regulatory definition of human subject is not met. Proposals for such activities will therefore be evaluated for compliance with requirements of the Privacy Rule.

- **Review of Exempt Research**

  Proposals that qualify as exempt research under 45 CFR 46 must be submitted to the IRB, per Columbia policy, and conducted in compliance with the Privacy Rule to the extent that the research involves the creation or receipt of protected health information about Columbia patients or research subjects, or the use or disclosure of protected health information maintained by or on behalf of Columbia. Research protocols that meet these criteria will have to be submitted to the IRB with all required documentation/form(s) prior to initiating the protocol.

  An investigator who seeks to conduct exempt research involving protected health information must:

  (1) Obtain from each research participant (or the participant's legal representative) a signed, written authorization to use and disclose the participant's protected health information for the research purpose; *or*

(2) Obtain documentation of a waiver of authorization to use and disclose participants' protected health information for the research purpose from the IRB; *or*

(3) Enter into a data use agreement with Columbia University which permits the investigator to conduct research using a Limited Data Set of protected health information.

Thus, despite the fact that such research is not subject to the requirements of 45 CFR 46, the Columbia IRB reviews all proposals for exempt research, and will also review the research for the purpose of granting a waiver of authorization, approving a research authorization form, or endorsing the use of a data use agreement under the Privacy Rule.

- **Research with Biological Materials**

  Biological materials and tissues are not in themselves protected health information under the Privacy Rule. However, protected health information accompanying such materials and tissues renders them subject to the Privacy Rule. All research performed using biological materials or tissues that are accompanied by protected health information and are maintained on behalf of Columbia patients or subjects in a research study shall be conducted consistent with this policy. Accordingly, the required HIPAA forms must be submitted to the IRB.

VII. EDUCATION TRAINING REQUIREMENTS

All Columbia faculty, staff, employees, students or agents that have, or will potentially have, access to protected health information must complete the HIPAA Training Module that is located in RASCAL.

HIPAA Web Site: http://www.cumc.columbia.edu/hipaa/

RASCAL Web Site: https://www.rascal.columbia.edu/

ISSUED: April 21, 2008