UNIVERSITY PHYSICIANS OF BROOKLYN, INC.

POLICY AND PROCEDURE

No: _____

Subject:	USE OF LIMITED DATA SETS	**Page** 1 **of** 3	
Prepared by:	Shoshana Milstein	**Original Issue Date:**	**NEW**
Reviewed by:	HIPAA Policy & Procedure Team	**Supersedes Date:**	**NONE**
Approved by:	HIPAA Oversight Committee	**Approval Date:**	**12/02**
		Distribution:	
		Issued by:	

I. Purpose: The use and disclosure of protected health information that is not fully de-identified is permitted for research, public health and healthcare operations providing that specific data elements have been removed- resulting in what is referred to as a "limited data set". This policy is designed to ensure that limited data sets are used and disclosed only pursuant to an appropriate data use agreement and in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its accompanying regulations.

II. Policy

A. Uses and Disclosures of Limited Data Sets

1. UPB may use protected health information (PHI), or disclose PHI to a business associate, to create a limited data set, whether or not the limited data set is to be used by UPB.
2. A limited data set may only be used or disclosed for the purposes of:
   a. Research;
   b. Public health; or
   c. Healthcare operations.

B. Limited Data Set Standard Requirements- A limited data set is PHI that excludes the following **direct** identifiers of the patient, his/her relatives, employers and household members:

1. Names;
2. Postal address information, other than town or city, State and zip code;
3. Telephone numbers;
4. Fax numbers;
5. E-mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/ license numbers;
11. Vehicle identifiers and serial numbers (including license plates);
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URL's);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints;
16. Full face photographic images and any comparable images.

C. Data Use Agreement- A limited data set may only be used if UPB obtains a data use agreement from the limited data set recipient. See attached Data Use Agreement.

1. Contents- The data use agreement must:
   a. Establish the permitted uses and disclosures of the information, including prohibiting further disclosures of the information in a manner that would violate the HIPAA privacy standards;
   b. Establish who is permitted to use or receive the limited data set;
   c. Provide that the limited data set recipient will:
      i. Not use or further disclose the information other than as permitted by the agreement or required by law;
      ii. Use appropriate safeguards to prevent use or disclosure other than as provided by the agreement;
      iii. Report to UPB any prohibited use or disclosure of which it becomes aware;
      iv. Ensure that any agents or contractors adhere to the same requirements of the data use agreement; and
      v. Not identify the information or contact the patients.
   d. Acknowledge that the recipient was notified of the additional confidentiality requirements applying to HIV- related information under New York State law.
2. Compliance- Any material breach, pattern of activity or violation of the data use agreement must be reported to UPB. UPB must then take reasonable steps to cure the breach or end the violation, and if unsuccessful:
   a. Discontinue disclosure of PHI to the recipient; and
   b. Report the problem to the Secretary of the Department of Health and Human Services.
3. UPB as Limited Data Set Recipient- If UPB receives a limited data set from another entity, it must follow all the requirements as set forth in the data use agreement executed by UPB and the entity disclosing the limited data set.

D. Pre-approval- All uses and disclosures of limited data sets must receive pre-approval by

the appropriate manager to ensure that all appropriate requirements have been met.

III. Procedure

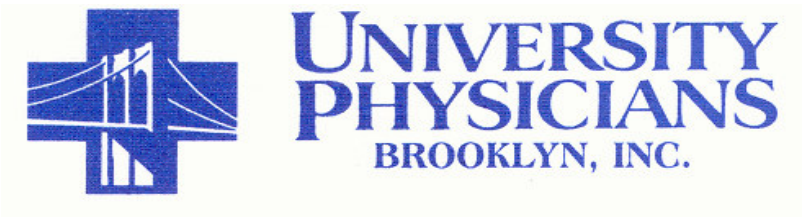
The development of the procedure section is the responsibility of the respective practice. It is dependent upon the unique needs of each practice's operating structure and shall be advanced and customized accordingly.

IV. Responsibilities: It is the responsibility of all medical staff members and practice staff members to comply with this policy. Medical staff members include physicians as well as allied health professionals. Practice staff members include all employees, medical or other students, trainees, residents, interns, volunteers, consultants, contractors and subcontractors at the practice.

V. Reasons for Revision- Regulatory changes

VI. Attachments- Data Use Agreement

VII. References- Standards for Privacy of Individually Identifiable Health Information, 45 CFR §164.514(e), 10 NYCRR Part 63



DATA USE AGREEMENT

This Data Use Agreement (the "Agreement") is effective as of _____ (the "Agreement Effective Date") by and between _____("Covered Entity") and _____("Data User").

RECITALS

WHEREAS, Covered Entity possesses Individually Identifiable Health Information that is protected under HIPAA (as hereinafter defined) and the HIPAA Regulations (as hereinafter defined), and is permitted to use or disclose such information only in accordance with HIPAA and the HIPAA Regulations;

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to disclose a Limited Data Set (as hereinafter defined) to Data User for use by Data User in performance of the Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to ensure that Data User will appropriately safeguard the Limited Data Set in accordance with HIPAA and the HIPAA Regulations; *and*

WHEREAS, Data User agrees to protect the privacy of the Limited Data Set in accordance with the terms and conditions of this Agreement, HIPAA and the HIPAA Regulations;

NOW THEREFORE, Covered Entity and Data User agree as follows:

1. **Definitions.** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as defined in HIPAA and the HIPAA Regulations.

a. "*HIPAA*" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

b. "*HIPAA Regulations*" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164.

c. "*Covered Entity*" means a health plan (as defined by HIPAA and the HIPAA Regulations), a health care clearinghouse (as defined by HIPAA and the HIPAA Regulations), or a health care provider (as defined by HIPAA and the HIPAA Regulations) who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.

d. "*Individually Identifiable Health Information*" means information that is a subset of health information, including demographic information collected from an individual, and;

1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

2) 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 the provision of health care to an individual; and

a) that identifies the individual; or

b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

e. "*Protected Health Information*" or "*PHI*" means Individually Identifiable Health Information that is transmitted by electronic media; maintained in any medium described in the definition of the term *electronic media* in the HIPAA Regulations; or transmitted or maintained in any other form or medium. Protected Health Information excludes Individually Identifiable Health Information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. § 1232g, and records described at 20 U.S.C. § 1232g(a)(4)(B)(iv).

2. **Obligations of Covered Entity.**

a. *Limited Data Set.* Covered Entity agrees to disclose the following Protected Health Information to Data User (the Limited Data Set):

_____

_____

_____

_____

_____

Such Limited Data Set shall not contain any of the following identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual: names; postal address information, other than town or city, State, and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

3. **Obligations of Data User.**

a. *Performance of Activities.* Data User may use and disclose the Limited Data Set received from Covered Entity only in connection with the performance of

___ research activities
___ public health activities
___ health care operations

Description of permitted activities:

_____

_____

_____

_____

_____

Data User shall limit the use or receipt of the Limited Data Set to the following individuals or classes of individuals who need the Limited Data Set for the performance of the Activities:

_____

_____

_____

_____

_____

For HIV-related information, Data User hereby acknowledges and agrees that Covered Entity has notified Data User that it is required to comply with the confidentiality, disclosure and re-disclosure requirements of 10 NYCRR Part 63.

b. *Nondisclosure Except As Provided In Agreement.* Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.

c. *Use Or Disclosure As If Covered Entity.* Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if Data User were a Covered Entity.

d. *Identification Of Individual.* Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.

e. *Disclosures Required By Law.* Data User shall not, without the prior written consent of Covered Entity, disclose the Limited Data Set on the basis that such disclosure is required by law without notifying Covered Entity so that Covered Entity shall have an opportunity to object to the disclosure and to seek appropriate relief. If Covered Entity objects to such disclosure, Data User shall refrain from disclosing the Limited Data Set until Covered Entity has exhausted all alternatives for relief.

f. *Safeguards.* Data User shall use any and all appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.

g. *Data User's Agents.* Data User shall not disclose the Limited Data Set to any agent or subcontractor of Data User except with the prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides the Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.

h. *Reporting.* Data User shall report to Covered Entity within 48 hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.

4. **Material Breach, Enforcement and Termination.**

a. *Term.* This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement is terminated in accordance with the provisions of Section 4.c. or upon the following date or event: _____.

b. *Covered Entity's Rights of Access and Inspection.* From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data User has breached this Agreement, Covered Entity may inspect the facilities, systems, books and records of Data User to monitor compliance with this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect, Data User's facilities, systems and procedures does not relieve Data User of its responsibility to comply with this

Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's enforcement or termination rights under this Agreement. The parties' respective rights and obligations under this Section 4.b. shall survive termination of the Agreement.

c. *Termination*. Covered Entity may terminate this Agreement:

1) immediately if Data User is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;

2) immediately if a finding or stipulation that Data User has violated any standard or requirement of HIPAA, the HIPAA Regulations, or any other security or privacy laws is made in any administrative or civil proceeding in which Data User has been joined; or

3) pursuant to Sections 4.d.(3) or 5.b. of this Agreement.

d. *Remedies*. If Covered Entity determines that Data User has breached or violated a material term of this Agreement, Covered Entity may, at its option, pursue any and all of the following remedies:

1) exercise any of its rights of access and inspection under Section 4.b. of this Agreement;

2) take any other reasonable steps that Covered Entity, in its sole discretion, shall deem necessary to cure such breach or end such violation; and/or

3) terminate this Agreement immediately.

e. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.

f. *Reporting to United States Department of Health and Human Services*. If Covered Entity's efforts to cure any breach or end any violation are unsuccessful, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's breach or violation to the Secretary of the United States Department of Health and Human Services, and Data User agrees that it shall not have or make any claim(s), whether at law, in equity, or under this Agreement, against Covered Entity with respect to such report(s).

g. *Return or Destruction of Records.* Upon termination of this Agreement for any reason, Data User shall return or destroy, as specified by Covered Entity, the Limited Data Set that Data User still maintains in any form, and shall retain no copies of such Limited Data Set. If Covered Entity, in its sole discretion, requires that Data User destroy the Limited Data Set, Data User shall certify to Covered Entity that the Limited Data Set has been destroyed. If return or destruction is not feasible, Data User shall inform Covered Entity of the reason it is not feasible and shall continue to extend the protections of this Agreement to such Limited Data Set and limit further use and disclosure of such Limited Data Set to those purposes that make the return or destruction of such Limited Data Set infeasible.

h. *Injunctions*. Covered Entity and Data User agree that any violation of the provisions of this Agreement may cause irreparable harm to Covered Entity. Accordingly, in addition to any other remedies available to Covered Entity at law, in equity, or under this Agreement, in the event of any violation by Data User of any of the provisions of this Agreement, or any explicit threat thereof, Covered Entity shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof, without any bond or other security being required and without the necessity of demonstrating actual damages. The parties' respective rights and obligations under this Section 4.h. shall survive termination of the Agreement.

i. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. The parties' respective rights and obligations under this Section 4.i. shall survive termination of the Agreement.

5. **Miscellaneous Terms.**

a. *State Law.* Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from an individual who is a subject of the PHI from which the Limited Data Set was created, or written authorization from any other person, where such authorization would be required under state law for such use or disclosure.

b. *Amendment.* Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set. Covered Entity may terminate this Agreement upon 5 days written notice in the event that Data User does not promptly enter into an amendment that Covered Entity, in its sole discretion, deems sufficient to ensure that Covered Entity will be able to comply with such laws and regulations.

c. *No Third Party Beneficiaries.* Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.

d. *Ambiguities*. The parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with applicable law protecting the privacy, security and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.

e. *Primacy.* To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to the subject matter of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

_____	_____
Name of Covered Entity	Name of Data User
_____	_____
Signature of Authorized Representative	Signature of Authorized Representative
_____	_____
Name of Authorized Representative	Name of Authorized Representative
_____	_____
Title of Authorized Representative	Title of Authorized Representative