POLICY NO. 719 LIMITED DATA SETS

SUBJECT: DE-IDENTIFICATION OF PROTECTED HEALTH INFORMATION/

PURPOSE:

To protect the privacy of patient health information by removing information that is individually identifiable when it is not necessary for the purpose in which the information is being used or disclosed.

To establish requirements for de-identification and re-identification of Protected Health Information (PHI) as well as the creation and use of limited data sets.

POLICY:

It is the policy of Harbor-UCLA Medical Center to set forth requirements for de-identification and re-identification of PHI. PHI is de-identified when the identifiers listed below (Procedures: Section I-A-B) have been removed and there is no basis to believe the information can be used to re-identify the individual. De-identified information is no PHI.

Unless Otherwise restricted or prohibited by other federal or state law, Harbor-UCLA Medical Center can use and share information as appropriate for the work of Harbor-UCLA Medical Center, without further restriction, if Harbor-UCLA Medical Center or another entity has taken steps to de-identify the information consistent with the requirements and restrictions of this Policy.

Harbor-UCLA Medical Center may use or disclose a limited data set that meets the requirements of this Policy, if Harbor-UCLA Medical Center enters into a data use agreement with the limited data set recipient (or with the data source, if Harbor-UCLA Medical Center will be the recipient of the limited data set) in accordance with the requirements of this Policy.

EFFECTIVE DATE: 04/14/03		SUPERSEDES:	
REVISED:			
REVIEWED: 12/08, 05/14, 07/17			
REVIEWED COMMIT	TEE: N/A		
APPROVED BY:			
Kim McKenzie, RN, MSN, CPHQ		Anish Mahajan, MD	
Chief	Executive Officer	Chief Medical Officer	
Patricia Soltero Sanchez, RN, BSN, MAOM			
	Chief Nursing Of	ficer	

Signature(s) on File.

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PROCEDURE:

- I. Requirement for de-identification of PHI
 - A. PHI may be de-identified by removing eighteen (18) specific identifiers of the individual or of the relatives, employers or household members of the individual, provided the entity does not have knowledge that the information could be used alone or in combination with other information to identify the individual, who is the subject of the information. The eighteen (18) specific identifiers are:
 - 1. Names
 - 2. All geographical subdivisions smaller than a state including:
 - a. Street Address
 - b. City
 - c. County
 - d. Precinct
 - e. Zip code and equivalent geocode except if the initial 3 digits of a zip code:
 - i. Represents a geographic unit in which combining all zip codes with the same initials contains more than 20,000 people, and
 - ii. The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to "000".
 - 3. All elements of dates (except year) directly related to an individual including:
 - a. Birth date
 - b. Admission date
 - c. Discharge date
 - d. Date of death, and
 - e. All ages over 89 (including data elements indicative of such age (including year), except
 - 4. Telephone numbers
 - 5. Fax Numbers
 - 6. E-mail addresses
 - 7. Social security numbers
 - 8. Medical record numbers
 - 9. Health plan beneficiary numbers
 - 10. Account numbers
 - 11. Certificate/license numbers

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- 12. Vehicle identifiers and serial numbers (including license plate numbers)
- 13. Device identifiers and serial numbers
- 14. Web Universal Resource Locators (URLs)
- 15. Internal Protocol (IP) Address numbers
- 16. Biometric identifiers, including finger/voice prints

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- 17. Full face photographic images and any comparable images and any comparable images
- 18. Any other unique identifying number, characteristic or code, except for a code or other means of re-identification as described in Section II below, and
- A. Harbor-UCLA Medical Center has no actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.
- B. Harbor-UCLA Medical Center may also demonstrate that health information is not individually identifiable if a person with appropriate knowledge and experience applying generally accepted statistical and scientific methods for rendering information not individually identifiable:
 - 1. Applies such principles/methods, determines that the risk is very small that the information could be used alone or in combination with other available information to identify an individual, and
 - 2. Documents the methods/results that justify the determination.

II. Re-identification Requirements

- A. Harbor-UCLA Medical Center may assign a code or other means of record identification to allow deidentified information to be re-identified provided the following conditions are met:
 - 1. The code or other means of record identification is not derived from or related to information about the individual.
 - Harbor-UCLA Medical Center does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism used for reidentification, and
 - 3. Harbor-UCLA Medical Center determines how and where these codes for re-identification are located and kept secure.

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B. Disclosure of the code or other means of record identification is considered a disclosure of PHI.

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- III. Requirements for a limited data set:
 - 1. A limited data set is PHI that excludes the following direct identifiers of the individual, or of relatives, employers or household members of the individual;
 - 2. Names;
 - 3. Postal address information, other than town or city, State and zip code;
 - 4. Telephone numbers;
 - 5. Fax numbers;
 - 6. Electronic mail addresses;
 - 7. Social Security numbers;
 - 8. Medical record numbers;
 - 9. Health plan beneficiary numbers (such as Medi-Cal Numbers);
 - 10. Account numbers;
 - 11. Certificate/license numbers;
 - 12. Vehicle identifiers and serial numbers, including license plate numbers;
 - 13. Web Universal Resource Locators (URLs);
 - 14. Internet Protocol (IP) address numbers;
 - 15. Biometric identifiers, including finger and voice prints; and
 - 16. Full face photographic images and any comparable images.
 - A. A limited data set may retain the following identifiers of the individual, or of the relatives, employers or household members of the individual:
 - 1. Town or city, Sate, and zip code; and
 - 2. Any element of dates directly related to an individual, including birth date, admission date, discharge date, date of death.
 - B. A limited data set may be used or disclosed only for the purpose of research, public health or health care operations.
 - C. Harbor-UCLA Medical Center needs not track or account for disclosures of limited data sets in an accounting of disclosures requested by an individual.
- IV. Contents of a data use agreement
 - A. Harbor-UCLA Medical Center may disclose a limited data set only if the entity receiving the limited data set enters into a written agreement with Harbor-UCLA Medical Center, in accordance with subjection (IV.) (B.) immediately below, that such entity will use or disclose the protected health information only as specified in the written agreement.
 - B. A data use agreement (Attachment A) between Harbor-UCLA Medical Center and the recipient of the limited data set must:

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- 1. Specify the permitted uses and disclosures of such information by the limited data set recipient. Harbor-UCLA Medical Center may not use the agreement to authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this Policy if done by Harbor-UCLA Medical Center.
- 2. Specify who is permitted to use of receive the limited data set; and
- 3. Specify that the limited data set recipient will:
 - a. Not use or further disclose the information other than as specified in the data use agreement or as otherwise required by law;
 - b. Use appropriate safeguards to prevent use of disclosure of the information other than as specified in the data use agreement;
 - c. Report to Harbor-UCLA Medical Center, if Harbor-UCLA Medical Center is the source of the limited data set, if the recipient becomes aware of any use or disclosure of the information not specified in its data use agreement with Harbor-UCLA Medical Center;
 - d. Ensure that any agent, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
 - e. Not identify the information or contact the individual whose data is being disclosed.
- V. If Harbor-UCLA Medical Center knows of a pattern of activity or practice of the limited data set recipient that constitutes a material breach or violation of the data use agreement, Harbor-UCLA Medical Center will take reasonable steps to cure the breach or end the violation as applicable, and, if such steps are unsuccessful, Harbor-UCLA Medical Center will:
 - A. Discontinues disclosure of PHI to the recipient; and
 - B. Reports the problem to the Secretary of the United States Department of Health and Human Services.
- VI. If Harbor-UCLA Medical Center receives a limited data set from another covered entity, Harbor-UCLA Medical Center must abide by the terms of a data use agreement.
- VII. Records Retention: All documents required to be created or completed under this policy and procedure will be retained for a period of at least seven years from the date of its creation or the date when it was last in effect, whichever is later.

REFERENCES:

- 1. Code of Federal Regulations 45 Part 160 and 164; Section 164.514(a)-(c), (e) "Other Requirements Relating to Uses and Disclosures of Protected Health Information.
- 2. Code of Federal Regulations 45 Part 160 and 164; Section 164.502 (d) "Uses and Disclosures of Protected Health Information: General Rules Uses and Disclosures of De-Identified Protected Health Information".

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DEPARTMENT OF HEALTH SERVICES COUNTY OF LOS ANGELES



MODEL DATA USE AGREEMENT

	is entered into effec "Covered Entity") and	day of 200_ ("	("Effective Data Set
Recipient).	• .		

RECITALS

WHEREAS, Covered Entity is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996, and regulations promulgated there under, including the Standards for Privacy of Individually Identifiable Health Information at 45 Code of Federal Regulations Parts 160 and 164 ("Privacy Regulations");

WHEREAS, the Privacy Regulations require Covered Entity to enter into an agreement with Data Set Recipient in order to mandate certain protections for the privacy and security of Protected Health Information, and those Regulations prohibit the disclosure to or use of a Limited Data Set by Data Set Recipient if such an agreement is not in place;

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties agree as follows:

DEFINITIONS

- 1.1 "<u>Disclose</u>" and "<u>Disclosure</u>" mean, with respect to the Limited Data Set, the release, transfer, provision of access to, or divulging in any other manner of the Limited Data Set outside Data Set Recipient's internal operations or to other than its employees.
- "Limited Data Set" means Protected Health Information that excludes certain direct identifiers of the individual, or of relatives, employers, or household members of the individual as set forth at 45 C.F.R. § 164.512(e)(2).
- "Required By Law" means a mandate contained in law that compels an entity to make a Use or Disclosure of Protected Health Information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or any administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing benefits.

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1.4 "Use" or "Uses" mean, with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Information within Data Set Recipient's

	internal operations.				
1.5	Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Regulations.				
	OBLIGATIONS OF DATA SET RECIPIENT				
2.1	Permitted Uses and Disclosures of the Limited Data Set. Data Set Recipient:				
	(a) shall Use or Disclose the Limited Data Set only for the following purpose(s):				
	The limited data set is to be used by only the Data Set Recipient.				
	The limited data set is to be used for				
	The Limited Data Set shall not be Used or Disclosed for any other purpose by the Data Set Recipient.				
·	(b) shall not Use or further Disclose the information other than as permitted by this Agreement, or as otherwise Required By Law.				
2.2	Adequate Safeguards. Data Set Recipient shall Use appropriate safeguards to prevent the Use or Disclosure of the information other than as provided by this Agreement.				
2.3	Reporting Non-Permitted Use or Disclosure. Data Set Recipient shall report to Covered Entity any Use or Disclosure of the information not permitted by this Agreement of which recipient becomes aware.				
2.4	<u>Use of Subcontractors and Agents</u> . Data Set Recipient shall require each of its agents and subcontractors that receive the Limited Data Set to execute a written agreement obligating the agent or subcontractor to comply with the terms of this Agreement.				
2.5	Prohibition on Identification and Contact. Data Set Recipient shall not identify the information or contact the individuals.				
	TERM AND TERMINATION				
3.1	This Agreement is effective (date) and expires (date).				
3.2	Upon Covered Entity's knowledge of a material breach or violation by Data Set Recipient of this Agreement, Covered Entity shall either:				

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- a) Provide an opportunity for Data Set Recipient to cure the breach or end the violation and terminate this Agreement if Data Set Recipient does not cure the breach or end the violation within the time specified by Covered Entity, or
- b) Immediately terminate the Agreement and discontinue the Disclosure of the Limited Data Set to the Data Set Recipient and to report the problem to the Secretary of U.S. Department of Health and Human Services.

SIGNATURES:	·
Data Set Recipient:	Date:
Covered Entity Represent	Date:
Privacy Officer	Date:
(Route to Privacy Officer for filing after completion	n)