

SINAI HEALTH SYSTEM INSTITUTIONAL REVIEW BOARD (IRB)
Application for the Use of Protected Health Information (PHI) Without Patient Authorization in
Research
Form A
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Today's Date: _____

Title of Project: _____

Principal Investigator: _____ Dept. _____

Chair: _____ Signature: _____

- 1. Type of Research:**
- a. Retrospective Study
 - b. Reviews Preparatory to Research
 - c. Decedent Information
 - d. Medical Registry Review
 - e. Limited Data Set (*attach limited data use agreement*)
 - f. Other _____
- 2. Purpose of Study:** _____
- 3. Study Start Date:** _____
- 4. Study Expiration Date:** _____

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- 5 PHI used for research purposes:**
- Complete health record(s), including all images (x-rays, photographs, etc.)
- Complete health record(s), excluding all images
- OR**
- Select from the following (check as many as apply):
- Discharge Summary
 - History and Physical Examination
 - Consultation Reports
 - AIDS (Acquired Immunodeficiency Syndrome) or HIV (Human Immunodeficiency Virus) infection
 - Mental health care or services
 - Psychotherapy Notes
 - Treatment for alcohol and/or drug abuse
 - Photographs, videotapes, digital or other images
 - Other (please specify) _____
 - Progress Notes
 - Laboratory Tests
 - X-ray reports

6 This information is to be disclosed to the following individuals or entity for the purpose of the research study:

Name	Address	Title	Purpose
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

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7. Does the requested PHI include decedent information? YES NO
If YES, the IRB may request documentation of death.
8. Please explain why the proposed research cannot be conducted without the IRB approval or an alteration to or waiver of authorization?

9. Please explain why the proposed research cannot be conducted without access to the requested PHI? _____
10. If this research involves more than minimal risk to a subject's privacy, please explain or attach a plan of how the PHI will be protected.

11. When will PHI be destroyed? _____ (Please specify date)
If you do not plan to destroy the PHI please attach justification for retaining the PHI or legal documentation.
12. How will rights or welfare of patients not be adversely affected by this study?

13. How will the uses and disclosures of PHI be accounted for in the patient's medical records?

I agree that the use and disclosure risks are reasonable in relations to the anticipated benefits of the research. I will not use or disclose the PHI beyond the expiration date, conduct unauthorized research with the PHI or reuse PHI obtained during the course of this study. I also agree **not** to remove PHI from the organization when preparing a protocol **preparatory** to research.

Signature of Principal Investigator

Date

Chair, Institutional Review Board

Date

FINAL STATUS: _____

IRB # _____