

Clinical Informatics Systems Data Use Attestation Form	SOP No.: CI-001
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	4 Pages

Instructions

1. Please read this form carefully.
2. Initial, sign and date this form to denote your acceptance and understanding of the policies outlined in this form. Please note that electronic signatures are not accepted.
3. This form can be returned to the UC Irvine Health Affairs Information Services, Clinical Informatics via email or fax.
 - a. Email. Please scan the signed form and save it in PDF format. Email the PDF file to CBMISupport@uci.edu
 - b. Fax the signed form to 714.456.2854

Statement of Liability for the End Users

This document defines the responsibilities of end users who use UC Irvine Health Affairs Information Services (HAIS), Clinical Informatics systems (including MyResearch, REDCap, Cohort Discovery Tool/i2b2) to collect and/or store sensitive patient data (Protected Health Information = PHI) extracted from clinical systems of care or collected for research purpose under the auspices of an approved IRB protocol.

1. _____ I agree that :
Initials

- ✓ Any PHI I receive or have access to as a researcher will be pursuant to UCI IRB approval OR another IRB's Approval and UCI IRB registration.
- ✓ Any identifiable patient data containing Protected Health Information (PHI) that I receive or have access to for the purpose of the research, will be accessed with IRB Approval and the subject's consent and documented HIPAA Research Authorization, or with IRB Approval where the IRB has granted a waiver of informed consent and a waiver of HIPAA Research Authorization.
- ✓ I will not engage in any other research uses not outlined in IRB or Human Research Protections approved documentation, unless I have consulted with the IRB and acquired the appropriate waivers or protocol modification prior to proceeding with this attestation.
- ✓ If I use decedent PHI, I confirm the following:
 1. The use or disclosure is solely for research on the PHI of decedents; and
 2. The protected health information (PHI) is necessary for research

purposes.

3. If requested by the covered entity (UCI), I will be required to provide documentation of the death of the individual(s).

2. _____ I will not discuss patient data (PHI) with unauthorized persons, agencies, etc.,
Initials without the written consent of the patient.

3. _____ If I wish to export PHI from the Clinical Informatics systems, I will implement UC
Initials Irvine-approved protections for PHI prior to doing so; therefore, I will not store PHI outside of the Clinical Informatics systems on any device or system unless the device, system, or the data itself is encrypted, including emails containing PHI.

CAUTION: I must not export the datasets containing PHI delivered by the Honest Broker outside of MyResearch portal without a written approval from the Compliance Office of School of Medicine.

4. _____ Storage of PHI on local devices (workstations, laptops, USB drives, portable
Initials hard drive, etc.) is strongly discouraged. If for unavoidable reasons I must store PHI on my local device, I will protect the device that contains PHI with the following control standards where appropriate by:

- ✓ Maintaining the most current versions of anti-virus software, anti-spyware software.
- ✓ Maintaining the most current versions of operating system updates, host-based firewall software and up-to-date security patches (Note: devices supported by UC Irvine Health Affairs IS on the UCI HS network domain will be automatically kept up-to-date) .
- ✓ Insuring the files containing PHI on the device is encrypted.
- ✓ Insuring data transmitted electronically is done so by utilizing encryption technology (SFTP, VPN, etc.).

5. _____ If I wish to export PHI from REDCap, I will export the data into my MyResearch
Initials account.

6. _____ I have read, understood, and signed the PHI Management Module for PHI Data
Initials Stewards at
<https://intranet2.ha.uci.edu/compliance/Training%20&%20Education/HIPAA%20Training/ucHIPAAem.pdf>

I have completed a **Human Research Protections training (e.g., CITI course) in the last five years** and the **HIPAA Research Tutorial** at <http://www.research.uci.edu/ora/train/tutorials.htm>

I will abide by all UC Irvine Health Affairs policies and procedures relating to patient privacy and the protection of PHI. I recognize that my failure to do so may subject me to disciplinary action.

7. Initials I will not use PHI obtained in my role as clinician for use in research.

8. Initials I will comply with all applicable UC Irvine policies pertaining to patient confidentiality and information security, including but are limited to:

Electronic Communications
Sec. 800-15: UCI Guidelines for the UC Electronic Communications Policy

Computing and Information Systems
Sec. 714-18: Computer and Network Use Policy

Authorized and Acceptable Use of Electronic Information Sec. 650-18

9. Initials I will abide by the following safe computing practices:

- ✓ I will protect the confidentiality of my User ID and password used to access the Clinical Informatics systems.
- ✓ I will use strong passwords; using a password-protected screensaver.
- ✓ I will never share my computer credentials (user name and password).
- ✓ I will always log off shared workstations before leaving the workstation.

10. Initials I will comply with all federal and state laws pertaining to patient confidentiality and my failure to do so may subject me to civil penalties and/or criminal proceedings, in addition to an assessment of related University costs. I will not share credentials (user name and password). If I do, I may be responsible for costs incurred by the University as a result.

11. Initials I will file an online incident report and notify the UC Irvine Privacy Office (714) 456- 3674 or the Security Office (714) 456-7349 as soon as reasonably possible upon my discovery of a loss or a suspected breach of a device containing PHI, and the UC Irvine PD (949-824-5223) if a device containing this data is lost or stolen.

12. Statement of Liability for Principal Investigators

Initials If I am a Principal Investigator on any study (contract, grant, and/or IRB application), in addition to the responsibilities delineated above, I understand that I am also accountable and liable for all Clinical Informatics systems users associated with my study adhering to the data use and security policies outlined in this attestation agreement. If I become aware of a breach of the policies outlined in this agreement, I will report the breach to the UC Irvine Privacy Office (714) 456- 3674 or the Security Office (714) 456-7349 as soon as reasonably possible

PRINT NAME

SIGNATURE

TITLE

DEPARTMENT

DATE