

<b>Clinical Research Systems Data Use Attestation Form</b>	<b>SOP No.: CI-001</b>
	<b>Version No.: 7</b>
	<b>Issue Date: 8/1/2019</b>
	<b>4 Pages</b>

### 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. Please scan the signed form, save it in PDF format, then mail the PDF file to CBMISupport@uci.edu

### Statement of Liability for the End Users

This document defines the responsibilities of end users who use UCI Health, Information Services, Clinical Research systems (including MyResearch, REDCap, Cohort Discovery Tool/i2b2, ACT/SHRINE) 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 :

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- ✓ 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 Research 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 Research 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 UCI Health 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 completed the required tutorials by the UCI Office of Research, Human  
Initials Research Protection in the last five years: CITI Human Research Protections Course and CITI Research and HIPAA Privacy Protections Course per <https://research.uci.edu/compliance/human-research-protections/researchers/training-and-education.html>

I will abide by all UCI Health 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. I will not use PHI obtained in my role as clinician for use in research.  
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8. I will comply with all applicable UC Irvine policies pertaining to patient  
Initials 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. I will abide by the following safe computing practices:

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- ✓ I will protect the confidentiality of my User ID and password used to access the Clinical Research 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. I will comply with all federal and state laws pertaining to patient confidentiality  
Initials 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. I will file an online incident report and notify the UC Irvine Privacy Office (714)  
Initials 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 Research 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

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PRINT NAME

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SIGNATURE

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TITLE

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DEPARTMENT

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DATE