



Opus Institutional Review Board

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HIPAA ATTACHMENT TO APPLICATION (COMPLIANCE FORM)

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	Principal Investigator
	Protocol
	Sponsor
	HIPAA Privacy Officer
Contact Information	
Address	
Phone	
Fax	
Email	

HIPAA Training

Please describe the training the PI and research staff have had concerning HIPAA awareness and security (or attach certificate from a seminar or course attended):

Recruitment

Please review the guidance document of OPUS IRB concerning acceptable recruitment practices

Indicate your recruitment process for this study

- Principal Investigator to recruit subjects from his own patient population.
- Principal Investigator to send IRB approved letter to colleagues asking for referrals of eligible subjects.

- Principal Investigator to send IRB approved "Dear Patient" letter to potential patients
- Principal Investigator to send IRB approved "Dear Patient" letter to colleagues for mailing to their patients
- IRB approved advertisement or media
 - Radio
 - TV
 - Newspaper
 - Video
 - Patient Education Newsletter
 - Patient Brochure
 - Poster
 - Other Printed Material
- Study does not collect PHI
- Waiver or partial waiver of authorization

Identifiers

OPUS IRB requests that subject identifiers within the data set be kept to the minimum necessary for the purpose of the study identified above. Please check those identifiers from the list below that are necessary for the study.

<input type="checkbox"/>	Name
<input type="checkbox"/>	Address
<input type="checkbox"/>	Dates (including date of birth, admission, discharge, treatment, date and time of death)
<input type="checkbox"/>	Telephone Numbers
<input type="checkbox"/>	Fax Numbers
<input type="checkbox"/>	Email Address
<input type="checkbox"/>	Social Security Number
<input type="checkbox"/>	Medical Record Number
<input type="checkbox"/>	Health Plan Beneficiary Number
<input type="checkbox"/>	Account Number
<input type="checkbox"/>	Certificate or License Number
<input type="checkbox"/>	Vehicle (VIN), license plate
<input type="checkbox"/>	Device serial number

<input type="checkbox"/>	Web URL
<input type="checkbox"/>	Internet Protocol (IP) Address
<input type="checkbox"/>	Biometric identifiers (finger or voice print)
<input type="checkbox"/>	Photograph Note: for studies involving photographic images, in addition to obscuring the subject's face, any tattoos, scars or other identifying characteristics are to be obscured. Please explain below if this study involves photography or other like imaging.
<input type="checkbox"/>	Any other unique identifying number, characteristic or code (including DNA, tissue samples):

Comments

List all persons or groups with whom the PHI will be shared (this information must be included in the Authorization for Use and Disclosure).

<input type="checkbox"/>	Other Investigators
<input type="checkbox"/>	Study Sponsor
<input type="checkbox"/>	CRO
<input type="checkbox"/>	SMO
<input type="checkbox"/>	Study Monitor
<input type="checkbox"/>	Statisticians
<input type="checkbox"/>	Central Lab
<input type="checkbox"/>	Clinic Lab(s): list all
<input type="checkbox"/>	Governmental Agencies (list all applicable)
<input type="checkbox"/>	IRB
<input type="checkbox"/>	IBC
<input type="checkbox"/>	Radiation Safety Committee / Radiation Safety Officer
<input type="checkbox"/>	Other Committee
<input type="checkbox"/>	Other

Security Measures

PHI associated with the study must be stored behind at least two of the following safeguards (mark all that apply):

<input type="checkbox"/>	Secure Network
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<input type="checkbox"/>	Password access
	Passwords are changed every months
<input type="checkbox"/>	Data is coded with a master list kept separately and securely
<input type="checkbox"/>	Locked office
<input type="checkbox"/>	Locked file cabinet
<input type="checkbox"/>	Data is de-identified

Security Measures

<input type="checkbox"/> Yes <input type="checkbox"/> No	A copy of the HIPAA Regulations is available in the research office
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Signature of Principle Investigator
**Sub-Investigator may sign in PI's absence*

Date