

REQUEST FOR APPROVAL OF AUTHORIZATION TO USE PROTECTED HEALTH INFORMATION

Date:

A. Principal Investigator Information	
Name:	
Phone Number:	
E-mail Address:	

B. Protocol Information	
Protocol Title:	

C. Protected Health Information (PHI) PHI = Health information + identifiers		
Will the project require the use or disclosure of PHI? *(If NO, you do not need to fill out this form) ** If the answer is YES, indicate the source of protected health information.	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> *NO
Name of Institution:		

D. Approval	
1.	Identify all individuals who will have access to data and PHI
	Individuals:
2.	Describe the PHI that will be gathered, used or disclosed as part of this research project.
	Describe:
3.	Describe the identifiers that will be gathered, used or disclosed as part of this research project. (What data variables are extracted from the medical record) Medical Record number, DOB, demographics, patient name

	Explain:
4	Explain why the research cannot practicably be conducted without requested PHI. The data is necessary to understand the statistics.
	Explain:

E. Data Security: explain safeguards and how data will be stored.	
1.	<p>Electronic (check all that apply):</p> <p><input type="checkbox"/> Secure network</p> <p><input type="checkbox"/> Password access</p> <p><input type="checkbox"/> Coded, with master list kept as a hard copy or on a secure network, separate from PHI/data</p> <p><input type="checkbox"/> Other: _____</p>
2.	<p>Hard copy (check all that apply):</p> <p><input type="checkbox"/> Locked suite</p> <p><input type="checkbox"/> Locked Filing Cabinet</p> <p><input type="checkbox"/> Locked office</p> <p><input type="checkbox"/> Data de-identified with master list secured and kept separately</p> <p><input type="checkbox"/> Other (explain)</p>

F. Sharing of PHI			
1.	Will the PHI be removed from the entity that owns the PHI?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
2a.	<p>Will the PHI be shared/used by others than P.I. and research staff?*if YES Mark all below that apply:</p> <p><input type="checkbox"/> Statistician</p> <p><input type="checkbox"/> Colleagues</p> <p><input type="checkbox"/> Other research laboratories</p> <p><input type="checkbox"/> Publications</p> <p><input type="checkbox"/> Data & Safety monitoring committees</p> <p><input type="checkbox"/> Sponsor</p> <p><input type="checkbox"/> Consultants</p> <p><input type="checkbox"/> Participants (Subjects)</p>	<input type="checkbox"/> *YES	<input type="checkbox"/> NO

	<input type="checkbox"/> Other(s) – explain: _____ _____		
2b.	If data will be shared, which of the following apply? NOT applicable <input type="checkbox"/> With identifiers <input type="checkbox"/> Without identifiers <input type="checkbox"/> With a linkage code <input type="checkbox"/> As a Limited Data Set (Requires data use agreement)		

G. Retention of PHI			
1.	<input type="checkbox"/> How long will the information be retained? <input type="checkbox"/> End of study <input type="checkbox"/> A set date (provide date): _____ <input type="checkbox"/> When data analysis is complete <input type="checkbox"/> Other (explain) after publication or research needs is met, to be determined. _____ _____		
2.	How will the information be destroyed ? <input type="checkbox"/> Electronic (explain) Delete the file: _____ <input type="checkbox"/> Hard copy (explain) hard copies will be shredded: _____		
3.	Is there a justification for retaining the identifiers? * If YES, what is the justification ? <input type="checkbox"/> Health Reasons (explain): _____ <input type="checkbox"/> Scientific (explain) to be able to support what is written, verify source of data: _____ <input type="checkbox"/> Legal(explain) _____ <input type="checkbox"/> Other (explain): _____	<input type="checkbox"/> *YES	<input type="checkbox"/> NO
4.	Will the stored PHI be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted ? *If YES please explain: _____	<input type="checkbox"/> *YES	<input type="checkbox"/> NO

I certify that the information provided in this request is complete and accurate:

- I understand that as the investigator, I have ultimate responsibility for the protection of confidential information and to ensure the privacy of research subjects and their protected health information.
- I agree to comply with all requirements of the Privacy Board as well as with all applicable federal, state and local laws.
- I have read the regulations and understand my responsibilities and the requirement for using and disclosing protected health information.

Name of PI or designee:	
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PI or Designee Signature

Date