Protocol Title: _____ IRB No. _____

Clinical Research Compliance Checklist

Privacy/Confidentiality

		YES	NO
1.	Is the proposed research project subject to the Common Rule or the FDA's human subjects protection regulations?		
2.	Will the research participant sign an informed consent reviewed by an IRB or a separate authorization for the use and disclosure of PHI for research along with any other legal permission related to the study?		
3.	Was the informed consent signed prior to the compliance date and did it provide authorization or express legal permission to use or disclose PHI for the research study?		
4. 4.a 4.b 4.c 4.d 4.e 4.f 4.g 4.h 4.i	Does the informed consent or authorization (obtained on or after the compliance date) include the § 164.508(c) and § 164.508(f) elements: "Specific and meaningful" description of info to be used or disclosed Identification of persons authorized to make requested use and disclosure Identification of persons to whom the requested use or disclosure may be made Description of each purpose of the requested use or disclosure Expiration date – "end of study' or 'none' for research database/depository Individuals' right to revoke Information may be subject to redisclosure Information used for treatment payment or health care operations Information that will not be used or disclosed although otherwise allowed		
5.	Does the research study only use or disclose de-identified data subject to the safe harbor?		
6. 6.a 6.b 6.c	Does the use and disclosure of research PHI qualify for a full or partial waiver of authorization under HIPAA by the IRB (or Privacy Board)? Minimal risk to privacy Cannot be practically conducted without the waiver Cannot practically be conducted without access to and use of PHI		
7.	Did research subject receive a Privacy Notice?		

By completing this checklist, I acknowledge that my department staff or I understand and have completed the compliance requirements to initiate a research protocol.

_____ _____
Principal Investigator Date

_____ _____
Research Coordinator (or person completing form) Date