HIPAA and Common Rule Compliance Checklist for medical records review studies requesting Waiver of Authorization (i.e., Waiver of Consent)

The HIPAA Privacy Rule*, 45 CFR 164 section 512(I) requires that requirements are satisfied in order to grant a waiver of individual authorization for research uses of Protected Health Information (PHI, i.e., person-identifiable information produced as a result of healthcare services). In addition to these criteria, the federal Common Rule (45 CFR 46 section 116(d)) stipulates that “whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

☐ The use or disclosure of PHI involves no more than minimal risk.

☐ Granting of waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.

☐ The project could not practicably be conducted without a waiver.

☐ The project could not practicably be conducted without use of PHI.

☐ The privacy risks are reasonable relative to the anticipated benefits of research.

☐ An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal.

☐ An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal.

☐ The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes.

☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If all of these conditions apply, a waiver of authorization may be granted and must be documented by a communication from the HRPP to the UCSD HIPAA Compliance Office.

*The HIPAA Privacy Rule became effective April of 2001 and covered entities such as the University of California must be in compliance with provisions of the rule not later than April of 2003. Voluntary compliance prior to that date is strongly encouraged.

Principal Investigator’s Signature: ____________________

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