Yale University

HIPAA PRIVACY

**Guidance on Withdrawal of Authorization for Research Uses and Disclosures**

The HIPAA Privacy Rule mandates that individuals may revoke an authorization, with limited exceptions, at any time provided that the revocation is in writing (45 CFR 46.508(b)(5)). Individuals must be informed of the ability to revoke authorizations through inclusion of a statement regarding revocation in order for the authorization to be valid (45 CFR 164.508 (c)(2)(i)). These requirements have been interpreted by many to mean that revocation of authorization can only be achieved through a written request. In response to comments by the Secretary's Advisory Committee on Human Research Protections, the Office of Civil Rights provided clarification on this issue when promulgating revisions to HIPAA in January 2013. In particular, the commentary states:

> "we also clarify that while the Privacy Rule requires that a revocation of authorization from an individual be in writing, uses and disclosures pursuant to an authorization are permissive and not required, and thus, a covered entity may cease using or disclosing protected health information pursuant to an authorization based on an individual's oral request if it chooses to do so." (Federal register 78(17) p5613)

Based on this clarification, we have chosen to incorporate both oral and written revocation options for research participants who wish to withdraw from future research participation including future collection of data about the withdrawing participant. It is our intent in doing so to minimize burden for research participants who wish to withdraw from further participation in the research, in keeping with the Belmont Report principle of Respect for Persons.

As outlined in the initial research authorization, such withdrawal does not preclude our ability to continue to use existing data to insure the integrity of the study and associated study oversight. We are obligated, however, to adhere to the withdrawal of authorization, whether verbal or in writing. Researchers are expected to have a robust process to ensure that the withdrawal of authorization is documented in study records in a way that ensures further PHI is not collected related to the withdrawing participant who has withdrawn authorization for further collection of PHI.