11c. Waiver or Modification of Informed Consent

Federal regulations permit the waiver or alteration of the informed consent document if a protocol meets very specific criteria… In order for the IRB to determine whether a protocol meets the criteria, it is essential that investigators seeking the waiver or alteration provide adequate justification for the request. IRB reviewers [will] look for the appropriate justification if a waiver or alteration is requested.

1. Have the criteria for waiver/medication of informed documentation been met?
    a. The consent form would be the only recorded linking the subject with the research, *and* a potential risk would be a breach in confidentiality. In such case, it is up to the subject when asked if they want documentation.
    b. Study is no more than minimal risk of harm to subject and involves no procedures which written consent is normally required outside the research context.
2. If informed consent documentation is waived, should the investigator be required to provide subjects with a written statement regarding the research?
3. If children are included, have the criteria for waiver of parental/guardian consent been met?
    a. IRB must determine parental/guardian permission is not a reasonable requirement to protect children as subjects.
    b. If a *waiver* or *modification* to required consent elements was proposed, have all the criteria been met?
    c. The research could not practicably be carried out with-out waiver or alteration, and when appropriate, the subject will be provided with pertinent information after participation.

From Bankert, E.A. & Amdur, R.J. (2006). *Institutional Review Board Management and Function*. (pp. 124-125). Burlington MA.: Jones & Bartlett Learning.