Rush University Medical Center
Policies and Procedures

Policy Number:	RA-IRB-201
Category Name:	Research
Title:	Alteration or Waiver of Informed Consent for Research Subjects
Type:	Policy and Procedure
Revised:	8/2014 (replaces 1/2011 version)

Applies To: Rush Investigators/Study Staff, Rush IRB Members, and IRB Administrative Staff

Policy: **The Rush IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent if it finds that all of the following criteria are satisfied:**

1) **The research could not practicably be carried out without the waiver or alteration;**
2) **The research involves no more than minimal risk to the subjects;**
3) **The waiver of alteration will not adversely affect the rights and welfare of the subjects;**
4) **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**
5) **The research is not regulated by the Food and Drug Administration (FDA).**
6) **If the research is funded by the Department of Defense (DoD), a Waiver of Consent has been obtained by the Assistant Secretary of Defense for Research and Engineering under Section 980 of Title 10 USC when the research involves intervention or interaction with a living individual (participant) for the primary purpose of obtaining data regarding the effect of the intervention or interaction. This stipulation does not include research that is not deemed human subjects research, meet the regulatory criteria for exemption under 45 CR 46 and 32 CFR 219, or research involving the collection or study of existing data, documents, records or specimens from living individuals.**

The Rush IRB may approve a waiver to obtain a signed consent form for some or all subjects if it finds either of the following:

1) **That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or**
2) **That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. This criterion also applies to FDA regulated research.**

Procedure:

As part of the New Project Application in the Rush Research Portal (RRP), Investigators seeking a waiver or alteration of consent must confirm that the research meets the criteria for a waiver or alteration of the consent requirements.

Any request for a waiver or alteration of the consent requirements will be approved only if the Rush IRB finds the Investigator's responses complete. In cases where the requirement to obtain written or signed consent has been waived, the Rush IRB will review a written description of the information that will be provided to subjects. Approval of any waiver or alteration of consent will be documented in the meeting minutes or expedited reviewer approval screen of the Rush Research Portal.

Requests by Investigators to obtain consent over the phone or via facsimile, rather than in person, will be considered by the Rush IRB on a case-by-case basis in compliance with this policy and Rush University Medical Center Operational Policy OP-0029.

Reference

45 CFR 46.116(d), 45 CFR 46.117, 21 CFR 56.109(c), DoD Instruction 3216.02 (dated November 8, 2011)

Last Reviewed: 8/6/2014