Michigan State University
Human Research Protection Program

Subject: Informed Consent

Sub-Topic: Waiver or Alteration of Informed Consent

Section: 6-4-B

This policy and procedure supersedes those previously drafted.

Approved by: Vice President of Research and Graduate Studies, 3-3-2005. Revision 1 approved by VP Research & Graduate Studies on 3-9-2008. Revision 2 approved by VP Research & Graduate Studies on 7-21-2011.

Related Sections: 6-3-A, 6-4-C, 7-3, 8-2, 8-3

“(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;”

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;”

(3) the research could not practicably be carried out without the waiver or alteration; and”

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.” 45 CFR 46.116

An investigator may request a waiver or an alteration of the requirement to obtain informed consent from subjects. Waiver of consent may apply to the use of existing private identifiable data. Alteration of consent may apply when the research involves incomplete disclosure or deception. See the Human Research Protection Program (HRPP) Manual 6-3-A “Incomplete Disclosure/Deception” for additional review requirements on projects that involve incomplete disclosure. The Institutional Review Board (IRB) may waive or alter the consent procedure by determining that the regulatory criteria for a waiver or alteration of the consent procedure are met. All the criteria have to be met for the IRB to grant a waiver or alteration of informed consent. When consent is waived, the IRB may require that the researchers provide subjects with a written statement regarding research.

The U.S. Department of Health and Human Services (45 CFR 46.116) waiver criteria cannot be used for projects subject to U.S. Food and Drug Administration (FDA) regulations and policies. FDA regulated research does not allow waivers unless for emergency use. See HRPP Manual 7-3 “Emergency Use of Investigational Drugs and Devices” for the requirements for emergency use.

Review and Documentation

Review and approval of waiver or alteration of consent follows the procedures as required by the level of review. See HRPP Manual 8-2 “Expedited Review Procedure”
and/or 8-3 “Full Board Review Procedure” for policies and procedures on review and
documentation required to waive or alter consent.

**Additional Considerations**
For research studies involving children, see HRPP Manual 6-4-C “Informed Consent:
Parental Permission and Child Assent” for waiver of parental permission criteria.