

| <b>Michigan State University<br/>Human Research Protection Program</b> |   |
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| <i>Subject:</i> Informed Consent                                       |   |
| <i>Sub-Topic:</i> Waiver or Alteration of Informed Consent             |   |
| <i>Section:</i> 6-4-B  | <i>This policy and procedure supersedes those previously drafted.</i>       |
| <i>Reviewed by:</i> IRB, URC, UGC, MSU Legal Counsel                   | <i>Approved by:</i> Vice President of Research and Graduate Studies, 3-3-05 |
| <i>Related Sections:</i> 6-3-A, 7-3                                    |   |

## **Policy**

There are instances in which an investigator may wish to waive or alter the requirement to obtain informed consent from subjects. Waiver conditions may apply, for example, to the use of existing data. An alteration of informed consent may apply when investigator' projects involve incomplete disclosure or deception. See Section 6-3-A, "Incomplete Disclosure/Deception" of the HRP Manual for additional review requirements on projects that involve incomplete disclosure.

### **DHHS – 45 CFR 116:**

- “(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.”

All the conditions have to be met for the Institutional Review Board (IRB) to grant a waiver or alteration of informed consent.

The DHHS waiver criteria above cannot be used for projects subject to Food and Drug Administration regulations and policies.

## **Procedure**

During the initial review, the IRB requires the investigator to explain and provide the rationale for each condition if a waiver or alteration of informed consent is requested.

For modifications to an approved project, the investigator will also be asked for an explanation if requesting a waiver or alteration of informed consent.

**Review and Documentation**

The IRB or an IRB member shall review the investigator's response to the waiver criteria and determine if the waiver criteria have been satisfied.

If the reviewer(s) determine that the waiver or alteration criteria have been satisfied, an IRB member will document that the conditions for a waiver or alteration have been met and why they met the criteria. A standard form shall be used for documentation.

For full board review protocols, the waiver or alteration of consent information shall be recorded in the minutes of the IRB meetings.

**Projects to which FDA policies and procedures apply**

See Section 7-3, "Emergency Use of Investigational Drugs and Devices", of the HRP Manual for FDA requirements for Waiver of Consent and Exceptions from Informed Consent Requirements for Emergency Research.