WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Compassionate and Expanded Use of Drugs and Devices
Section	
Form Date	11/2/06
Approvals	Office of the General Counsel 2/8/07, Steering Committee 03/12/07, Administrative Approval 03/26/07

Background/Policy

Investigational drugs and devices may be used for the treatment of serious or debilitating conditions either for a single subject or for a small group of subjects. The United States Food and Drug Administration (FDA) recognizes that there are circumstances in which patients with a serious, and potentially debilitating or life-threatening condition have no other treatment options other than to receive an investigational drug or device for treatment of those conditions.

Sponsors will frequently refer to this type of treatment use as "compassionate use". However, the use of this term "compassionate" is not recognized by the Food and Drug Administration (FDA) or the Office for Human Research Protections (OHRP) for investigational drugs or biologics and must not be confused with an emergency single time use of a test article. (See HIC Policy/Procedure: Emergency Single Time Use of a Test Article".) However, compassionate use of an investigational device can be approved under an existing Investigational Device Exemption, according to the FDA.

The use of investigational drugs and devices for expanded treatment **will always** require the submission of a prospective research protocol to the Wayne State University (WSU) Institutional Review Board (IRB) for review and approval prior to the use.

For more specific information on expanded use of investigational drugs or biologics for treatment purposes, please refer to the HIC Policy/Procedure: "Investigational Drug Research".

For more specific information on expanded use (compassionate use) of investigational devices for treatment purposes, please refer to the HIC Policy/Procedure: "Approved and Unapproved Research with Devices".