WAYNE STATE UNIVERSITY

Wayne State University Human Investigation Committee	
SUBJECT	Off-Label Use for Clinical Care
Section	
Form Date	10/2/06
Approvals	11/10/06 Administrative Review

Background and Policy

Good medical practice and the best of interest of patients require physicians to use commercially available drugs, biologics, and devices according to their best knowledge and judgment. If, in the treatment of individual patients, physicians use a product for an indication not in the approved labeling, they have the responsibility to be well-informed about the product, to base their use of the product on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. (FDA Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators 1998 Update. "Off Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices").

The use of a product in this manner as part of the practice of medicine does not require the submission of a research protocol with an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE) for review by the Wayne State University (WSU) Institutional Review Board (IRB).

The investigational use of approved marketed products differs from the situation described above. "Investigational Use" means the use of an approved product in the context of a clinical study protocol. When the intent of the investigational use of a drug is to develop information about the product's safety or efficacy, submission of a protocol to the IRB for review and approval is required unless the criteria for exemptions are met. See HIC Policy/Procedures: "Investigational Drug Research" & Research with Devices" for more information on INDs and IDEs.

Further information may be requested from the HIC Administrative Office at (313) 577-1628.