WAYNE STATE UNIVERSITY

HIC Policy/ Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Closure of a Research Protocol
Section	
Form Date	10/09/06
Approvals	Steering Committee 6/21/06; Revised Steering Committee 11/03/06; Administrative Approval 11/08/06

Background

The Department of Health and Human Services (DHHS) regulations (45 CFR 46), Veteran's Administration (VA) regulations (38 CFR 16) and Food and Drug Administration (FDA) regulations (21 CFR 50 and 21 CFR 56) require prompt reporting to the Institutional Review Board (IRB) of proposed changes in a research activity. The Wayne State University (WSU) Human Investigation Committee (HIC) requires that investigators submit a closure form when a protocol is closed. Failure to submit a closure form for all closed studies, including those that have expired or lapsed, may result in limitations on the investigator's ability to submit future studies. (Please see Continuation/Renewal of a Protocol SOP)

A study can be closed if it no longer meets the definition of "human participant research" (See definitions).

Definitions

Closure: A protocol is closed when the Principal Investigator determines that the study no longer meets the definition of "human participant research" and submits a Closure form to the HIC.

Research:

1. Under DHHS regulations a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2. Under FDA regulations any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Food, Drugs, and Cosmetics Act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug, and Cosmetics Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

Human Participant (Subject):

1. Under DHHS regulations a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual or (b) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
2. Under FDA regulation an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used.

Human Participants Research:

1. Meets the DHHS definition of "research" and involves human subjects as defined by DHHS regulations; OR
2. Meets the FDA definition of "research" and involves "human subjects" as defined by FDA regulations.

SCOPE

Criteria for Study Closure:

A study may be closed when all of the following apply:

1. All collection of data involving interventions and interactions has been completed for all participants. No further contact with participants is necessary.
2. All collection of private identifiable information has been completed for all study participants. No further collection of data/information from or about the individuals will be obtained.
3. If the study involves the testing of a medical device with tissue specimens where the data will be submitted to or held for inspection by the FDA, the study may be closed when all collection and use of the specimens for the research protocol has ended.
4. If the study is funded and the sponsor agrees to or recommends closure.

Retention of Identifiers after Study Closure:

If a Principal Investigator (PI) conducting human participant research (as defined above) is analyzing identifiable private information but is not obtaining any new information, the study does not meet all criteria for human participant research and may be closed. The identifiable information may be retained in the database so that on-going analysis can proceed. If the database containing identifiers is transferred or shared with another investigator, IRB review and approval must be obtained.

Retention of Specimens after Study Closure:

If a PI conducted a study on specimens that constituted human subject research, those specimens may be retained for future use in research if the participant, at the time of consent for the study, permitted the retention for this purpose. If the specimens are identified, this information may be retained in the database and on-going analysis can proceed after study closure as long as no new specimens are obtained and added to the database. If the specimen bank containing identifiers is transferred or shared with another PI, IRB review and approval of the new research study must be obtained. If specimens are unidentifiable, these can be kept as well. If the participant requested that they be contacted for permission to use specimens in a future protocol, the PI must do so prior to using the specimens in a new research project.

HIC Policy/Procedures

The PI is responsible for providing the HIC with any changes to the protocol. Once it has been determined that the protocol can be closed, the following actions are required:

1. Complete and submit a *Protocol Closure Form*.
2. Attach any documentation received from the sponsor regarding the closure of the study.
3. If available, attach any other new findings/publications that relate to the study.

Upon receipt of the *Protocol Closure Form* in the HIC office:

1. The HIC staff will review the documents for completeness. Investigators will be contacted to provide clarification and/or additional documentation if necessary.
2. The HIC Chairperson or designee will determine if closure of the study is appropriate.
3. When closure is appropriate the original closure form will be placed in the HIC protocol file and a copy of the signed closure form will be mailed to the PI for his/her records.
4. The complete study file will be removed from the active files and stored for a minimum of three years and up to five years from the date of the closure

All closures of protocols will be reported to the IRB that approved it initially.