WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
Subject	Exempt Review
Form Date	December 2006 (Rev. 7/14/10)
Approvals	Office of General Counsel 12/04/06, Steering Committee 12/19/06, Administrative Review 03/06/07, Administrative Approval 9/30/10

Background:

Human participant research is an activity that must meet either 1)The Department of Health and Human Services (HHS) regulations'(45 CFR 46) definition of "research" and involves "human subjects," or 2) the VA regulations' (38 CFR 16) and Food and Drug Administration (FDA) regulations' (21 CFR 50 and 21 CFR 56) definition of "research" and involves "human subjects." Projects that do not meet the definition of human subjects (participant) and the definition of research are not reviewed under these regulations. See the Human Investigation Committee (HIC) website Home Page "Human Participant Research-How is it Defined?" for further information.

An investigator cannot exempt his/her research project from IRB review and concurrence. Instead, the Wayne State University (WSU) HIC) chairperson or his/her designee must determine that a project is eligible for exemption. For VA research, the IRB chair or an IRB members designated by the chair must make exemption determinations. Any study that the HIC chairperson or his/her designee believes is not exempt must be reviewed by either an *expedited* or *full board* review process. A research project meeting the criteria for exemption cannot start until after the HIC chairperson or his/her designee has given concurrence of exemption. Retroactive concurrence or review cannot occur.

Definitions:

Human participant (subject):

1. Under HHS regulations "human subject" means 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) with a person's identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. 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 participant is or may readily be ascertained

by the investigator or associated with the information) in order for obtaining to constitute research involving human participants.

2. Under FDA regulations "human participant" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A participant may be either a healthy individual or a patient. For research involving medical devices a human participant is also an individual on whose specimen an investigational device is used.

Research:

1. Under DHHS regulations "research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2. Under FDA regulations research means any experiment that involves a test article and one or more human subjects, and that either 1) 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 2) 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, and is defined as a systematic investigation designed to develop or contribute to generalizable knowledge.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Exempt research: Human participant research where the entire research project falls within one or more of the six specific regulatory categories (see below) and satisfies all institutional policies and procedures.

Consent Process: The process by which a human participant is informed (understands) what a study entails before voluntarily agreeing (consenting) to participate. The informed consent process begins with recruitment and obtaining a signature on an informed consent document and continues through and beyond the completion of the study.

Scientific Review:

Before the HIC can review a protocol involving the use of human participants in research, the protocol must be reviewed for scientific merit by the Principal Investigator's (PI) department. Various departments conduct this scientific review in different ways and the WSU Institutional Review Board committees (IRBs) will accept any of these methods as long as the department Chair and/or his/her designee certifies on the first page of the Medical/Behavioral Protocol Summary Form that the scientific review has been completed. In addition to scientific review, the department is responsible for certifying that appropriate support and resources will be provided to conduct the study.

For all research involving cancer and human participants, the Protocol Review Committee of the Karmanos Cancer Institute must review the research protocol. The approval of the Protocol Review Committee must be submitted to the HIC as part of the package of material that is required by the HIC before the IRB review can be initiated.

For all research involving human participants at the John D. Dingell VA Medical Center (JDD VAMC), the protocol must be reviewed by the JDD VAMC Clinical Investigation Committee (CIC) before the protocol can be reviewed by the HIC. The approval of the CIC must be submitted to the HIC as part of the package of materials that is required by the HIC before their review can be initiated. [VA 1200.5]

All research involving human participants whose Principal Investigator is a faculty member in the Department of Psychiatry and Behavioral Neuroscience, must first be reviewed by the Department Review Board. This approval must be submitted to the HIC as a part of the package of material that is required by the HIC before the review can be initiated.

While not a scientific review, the Detroit Medical Center (DMC) conducts a mandatory pre-review on all protocols to be conducted in their institutions. This process involves a review for liability and privacy issues. This review can occur concurrently with the IRB review process. A study cannot start until both the HIC and DMC reviews have been completed and official approval notice of both have been received.

All research involving human participants at the Oakwood Healthcare System must be reviewed by the Clinical Trials Office. A Research Project Administrative Approval (RPAA) document must be included with all submissions to the HIC. Resident projects require a separate review from the Resident Research Review Committee and that approval must be included (in addition to the RPAA) with a protocol submission to the HIC.

HIC Procedures:

The HIC will maintain an updated website which provides detailed guidelines for submission requirements of new protocols.

Medical Protocols: The HIC Chairperson or his/her designee reviews the submitted research project, Medical Exemption Form and attachments, requests modifications, and provides administrative approval. In his/her absence, the chairperson from one of the three medical IRB's is appointed to conduct the review.

Behavioral Protocols: The Behavioral IRB Chairperson or his/her designee reviews the submitted research project, Medical/Behavioral Protocol Summary Form and attachments, requests modifications, and provides administrative approval. In his/her absence, the Vice Chairperson, the HIC Chairperson, or an experienced Behavioral IRB member is designated to conduct the review.

The HIC Chairperson or his/her designee conducts the exempt review process with careful consideration given to review of the risks, benefits, provisions for confidentiality, protection of participant voluntarism, and the process of informed consent. Exempt research is evaluated to determine whether it fulfills WSU's ethical standards. This review includes the following:

- The research holds out no more than minimal risk to participants.
- Selection of participants is equitable.

- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- If there are interactions with participants, there will be a consent process that will disclose such information as:
    - That the activity involves research
    - A description of the procedures
    - Name and contact information for the investigator
    - There are adequate provisions to maintain the privacy interests of participants.

As part of his/her review, the HIC Chairperson or his/her designee has one of three options:

1. Concur that the exemption category applies to the proposed research
2. Determine that a different exemption category applies, or
3. Require resubmission of a research project that would be reviewed and approved under an expedited or full board review process

All research projects that the HIC Chairperson or designee concurs are eligible for exemption are reported to the applicable IRB committee.

Approval of research under an exemption is given for an indefinite time period. Re-review is not required unless the investigator proposes changes to the research project. All investigator-requested changes must be submitted on a Medical/Behavioral Amendment Form and approved prior to implementation of changes (Please see the HIC Policy/Procedure "Amendments to the Research Protocols".)

The Principal Investigator will be notified in writing of all exempt review decisions within 7 to 10 business days (Please see the HIC Policy/Procedures "Notification of IRB Decisions to Principal Investigator and PI Response Requirements".

Exemption Categories:

Under federal regulations (45 CFR 46.101), research activities in which the only involvement of human participant will be in one or more of the following categories are eligible for exemption by the WSU Institutional Review Boards.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
    a. Research on regular and special education instructional strategies, or
    b. Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless:
    a. Information obtained is recorded in such a manner that human participants can be identified directly or through identifiers linked to the participants; and
    b. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, loss of insurability, or reputation.

NOTE: This category does NOT apply to research with children, except when:
1. the project will be using educational tests, or
2. public behavior is being observed, as long as the investigator(s) do not participate in the activities.

3. Research involving the use of educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 above, if:
    a. The human participants are elected or appointed public officials or candidates for public office, or
    b. Federal statute(s) require(s), without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified directly or through identifiers linked to the participants.

NOTE: To qualify for this exemption, the data, documents, records, or specimens must be in existence BEFORE the project begins.

5. Research and demonstration projects which are conducted by, or participant to, the approval of Department or Agency heads and which are designed to study, evaluate, or otherwise examine:
    a. Public benefit or service programs, or
    b. Procedures for obtaining benefits or services under those programs, or
    c. Possible changes in, or alternatives to, those programs or procedures,
    d. Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies if:
    a. Wholesome foods without additives are consumed, or
    b. Food is consumed that contains a food ingredient at or below the level and for a use found to be safe; or agricultural, chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Human participant research that CANNOT be Exempt

- Projects that involve prisoners per HHS regulations.

- Projects that are FDA-regulated with the exception of food testing.

- Projects in which the investigator's records have identifiers linking directly to an individual research participant (e.g., names, social security number, hospital admission number, specimen number, etc.)

- Projects that could result in disclosure and could reasonably place the participant at risk for criminal or civil liability or be damaging to the participants' financial standing, employability, loss of insurability or reputation.