MORGAN STATE UNIVERSITY

PROCEDURES UNDER THE POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

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Morgan State University ("University" or "MSU") has established a Policy for the Protection of Human Subjects in Research that sets forth the expectations for the protection of human subjects in research and related activities conducted under the auspices of the University. This document sets forth the procedures (the "Procedures") the University must follow to engage in the research and related activities involving human subjects.

1. Human Subjects Research - Definitions

A human subject is a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Research as defined by the Department of Health and Human Services means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). Research is considered synonymous with Clinical Investigation as defined by the Food and Drug Administration (FDA). The following activities are considered not research by DHHS:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

2. Guiding Principles

The MSU Institutional Review Board (IRB) is charged with protecting the rights and welfare of human research subjects, specifically ensuring that those individuals participating in research are not subject to undue or inappropriate risks, that participation remains a voluntary right, and that the conduct of research is upheld as a privilege.

The IRB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report)". In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) are upheld. The University has chosen to require that research covered by its assurance be conducted in accordance with the requirements of 45 CFR 46, regardless of the source of funding, or whether there is funding. These principles are to be upheld by all individuals involved in human subjects research under the auspices of the University, including researchers and research staff, the IRB administrator, the IRB and IRB support staff.

3. Authority

The administrative authority for the protection of human subjects at the University has been delegated to the Vice President for Research and Economic Development, or designee.

The IRB is administratively responsible to the Vice President for Research and Economic Development. The IRB is authorized to review human subjects research in accordance with the University Policy on Research with Human Subjects and consistent with federal regulations (45 CFR 46).

4. Institutional Review Board (IRB)

A. Membership Composition. The IRB must be composed of sufficient members (no less than five) with varying educational backgrounds and expertise to assure complete and adequate review of research projects and activities conducted by the University. In addition to a balance of research expertise, the ~~Committee~~ IRB shall also include persons able to determine the acceptability of a research proposal with respect to institutional commitments and regulations, applicable law, standards of professional conduct and practice and community attitudes.

The members of the IRB are nominated by the IRB Administrator, who is the University's Director of Research Compliance, in consultation with the Vice President for Research and Economic Development. Each member of the IRB is appointed for an initial 3-year term which is renewable for yearly terms after the initial 3 years.

No Board may consist entirely of men or entirely of women, or entirely of members of one profession. The Board shall include at least one member whose primary concerns are in

nonscientific areas; for example: lawyers, ethicists, members of the clergy. The Board shall also include at least one member who is not otherwise affiliated with the institution.

The members shall be identified to DHHS by name, earned degrees (if any), position or occupation, representative capacity. In conforming with federal regulations, all permanent changes of membership, replacement or additions, are reported to DHHS (OHRP, National Institutes of Health, DHHS, Bethesda, Maryland 20892).

B. IRB Minutes

The IRB Office shall prepare and maintain adequate documentation of IRB deliberations. Minutes of the Board meetings shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the Board; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the University Committee.

C. IRB Records

The IRB Office shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent document, progress reports submitted by research investigators and reports of injuries to subjects.

2. Records of continuing review activities.

3. Copies of all correspondence between the Board and the research investigators.

4. A list of IRB members as required by 45 CFR 46.103(b)(3).

The Division of Research and Economic Development shall provide adequate resources for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IRB approval period for the activity.

5. Investigator Training

All investigators who will be collecting data from human subjects, obtaining the informed consent of human subjects, or accessing identifiable human subjects data, as well as faculty supervisors of student protocols, must complete human subjects training prior to receiving IRB

approval. The University provides access to online human subjects training through the CITI program.

An overall score of 80% is required. Initial CITI human subjects training is good for three years. Once initial training has been completed, refresher training is required, which is also good for three (3) years. For those investigators that have previously met comparable and documented IRB human subjects training requirements by taking courses offered outside of the University, that training is also good for three (3) years. When training needs to be renewed, investigators may take the CITI refresher course. For training requirements and registration instructions, contact the Director of Research Compliance in the Division of Research and Economic Development.

6. Submission of Protocols

Prior to research initiation, the IRB review must find that all criteria for IRB approval outlined below are met, or exemption granted, as applicable. Required supporting documents include the following as appropriate:

- Project Abstract - this should be written so that someone who is not familiar with your field of research will understand the activity
- Consent forms
- Assent forms
- Letter of support if data collection site is a school or after-school program
- Any advertising materials (flyers, posters, emails to prospective participants, etc.)
- Surveys, interview questions, instruments
- Any activity subjects will perform
- Documentation for any devices used during data collection
- Certificates of human subjects protection training
- Any additional materials that seem appropriate to your study

7. Review of Protocols

The IRB also evaluates whether resources are adequate to protect subjects' rights and welfare, including but not limited to, Principal Investigator (PI) qualifications and adequate research facilities.

The IRB may approve, require modification to secure approval (deferred approval), or disapprove research proposals. In some cases, exemptions may be granted, but any exemption requires the IRB Administrator to conduct a limited review to make the determination required for Exempt Research (see list of Exempt Categories below).

Research which is approved by the IRB may be disallowed by the University Official, who is deemed to be the President or designee (including but not limited to Vice President for Research and Economic Development and/or the Provost). If research is approved by the IRB but not permitted by the University, the appropriate institutional authority will promptly notify the IRB Administrator that the research cannot be conducted, including the reasons for that determination.

No official or office of the University may approve a research activity that has been disapproved by the IRB, and no external body or official may override IRB disapprovals, nor apply undue pressure on the IRB to approve a research study or reverse a decision.

The IRB may suspend, place restrictions upon, or terminate approval of research activities falling within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with unexpected serious harm to subjects.

The IRB may have the consent process or the research procedures of any research study under its jurisdiction observed by a third party if the IRB determines that such observation is indicated.

Deliberations, decisions, findings, and actions of the IRB associated with research activities are considered confidential, except as appropriate. This information is reported to appropriate institutional officials as required by law and/or policies of the IRB. Failure to adhere to this provision may be cause for removal of a member from the IRB.

8. Criteria for Approval

Based on the IRB's review of information provided by the researcher or study team, and in accordance with appropriate regulations, the IRB may grant approval of research, deferred approval or disapproval, if it determines that all of the following requirements are satisfied or not:

- Risks to subjects are minimized by using procedures that (1) are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. This includes assessing the adequacy of the setting or facilities where the research will take place.

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies/procedures/activities subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, adult individuals lacking consent capacity, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with and to the extent required by relevant regulations.
- Informed consent will be appropriately documented, or appropriately waived, in accordance with relevant regulations.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, adult individuals lacking consent capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the research proposal to protect the rights and welfare of these subjects.

Categories of EXEMPT Research

Exempt Category1:

EDUCATIONAL EXEMPTION

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Most educational research on regular and special educational instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods may be exempt under this category.

If the research involves significant time and attention away from the delivery of regular curriculum or withholding of standard educational content, this exemption would not apply. Also, there must be protection against negative impact on employment if

instructors are being evaluated. Research involving randomization to an unproven educational technique, or research conducted by supervisors involved in employment decisions may not be approvable under this exemption.

Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

Exempt Category 2:

SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:

(i)The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review*.

This category involves interactions (verbal and written responses) and data collection only.

The data collection can include audio or video recordings. Research involving "interventions" would not be approvable under this category. Interventions include manipulation of the environment or physical procedures to collection information, such as a cheek swab.

Applicability to vulnerable populations

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption only when it related to educational tests or observations in which the investigators don't participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited IRB review.

Exempt Category 3:

BENIGN BEHAVIORAL INTERVENTION

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review*.

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Applicability to vulnerable populations:

- Pregnant women who are adults *may* be included in this type of research
- Research that targets a prisoner population is *not* eligible for this exemption.
- Research that could include children is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving persons with impaired decision-making capacity is *not* eligible for this exemption.

Exempt Category 4

SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/BIOSPECIMENS)

Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(ii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iii)The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

- The requirement that all study data be existing at the time of IRB submission has been eliminated. Data under this exemption may be both retrospective and prospective.
- The requirement that the study involves data only has been eliminated. The research may also involve the use of specimens.
- Creating a de-identified dataset for analysis is still an approvable option and continues to be the most straight-forward approach.
- If investigators need to retain data that contains any HIPAA elements or need to retain a linking list, then appropriate HIPAA protections could make the project approvable. Depending on the circumstances of the data, the HIPAA protections might include a Business Associate Agreement, a Data Use Agreement or a waiver of HIPAA authorization with accounting of disclosures.
- Certain sources of publicly available data require the recipient to sign an agreement outlining restrictions on access, use, security and transfer. Most often, those agreements will need review by the University's Office of General Counsel.

It is important to note the Exemption Category 4 only applies to the *re-use* of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another approval path would be required.

Applicability to vulnerable populations:

- Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn't designed to recruit prisoners and prisoners were only incidental subjects of the research
- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

Exempt Category 5

PUBLIC BENEFIT/SERVICE PROGRAM RESEARCH (FEDERAL DEMONSTRATION PROJECTS)

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Exempt Category 6:

TASTE/FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE

Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or if a 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.

Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.
- Research involving decisionally-impaired persons could be allowed if their inclusion was justified.

Exempt Category 7:

STORAGE / MAINTENANCE OF IDENTIFIABLE DATA/BIOSPECIMENS OBTAINED WITH "BROAD CONSENT"

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR § 46.111(a)(8).

Research with vulnerable populations may be approvable with this exemption:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

Exempt Category 8:

USE OF IDENTIFIABLE DATA/BIOSPECIMENS OBTAINED WITH "BROAD CONSENT"

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR § 46 .116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § .117;

(iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

Research with vulnerable populations may be approvable with this exemption:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

The IRB may use an expedited review procedure to review any of the following:

- Research which involves only procedures listed in one or more of the Expedited Research Categories below, and which the reviewer determines involves no greater than minimal risk
- Renewals or modifications to research previously approved under expedited procedures provided the research continues to meet the Expedited Research Categories below and any modifications do not substantially increase risk to subjects
- Minor changes in research previously approved by the convened IRB

Categories of Expedited Research

Category 1

Clinical studies of drugs and medical devices only when either condition below is met:

- Research on drugs for which an investigational new drug application (21 CFR 312) is not required. Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review; or
- Research on medical devices for which (1) an investigational device exemption application (21 CFR 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3

Prospective collection of biospecimens for research purposes by noninvasive means. Examples include:

- Hair and nail clippings in a nondisfiguring manner;

- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or
- Sputum collected after saline mist nebulization.

Category 4

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples include:

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography; electroencephalography, thermography detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Note that some research in this category may be exempt from the federal regulations or IU HRPP Policy and procedure. This listing refers only to research that is not exempt.

Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note that some research in this category may be exempt from federal regulations or IU HRPP Policy and procedure. This listing refers only to research that is not exempt.

Category 8

Continuing review (i.e., renewal) of research previously approved by the convened IRB as follows:

- where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects; or
- where no subjects have been enrolled and no additional risks have been identified; or
- where the remaining research activities are limited to data analysis.

Category 9

Continuing review (i.e., renewal) of research, not conducted under an investigational new drug application or investigational device exemption, where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Continuing Review

The IRB conducts continuing review of research at intervals appropriate to the degree of risk, but not less than once per year for approved research.

Projects extending beyond a period of one year require at least annual review and approval by the IRB. The Board may request more frequent reviews when the element of risk and the nature of the project warrant them. The Board uses written procedures for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no substantive changes have occurred since last IRB review. For this purpose, the Board will inform the investigator in writing about its decision whether or not project review more often than the investigators are required. The IRB Chair will keep track of these special requirements on their respective calendars to ensure that the requirements will be enacted.

If the research protocol remains substantively unchanged, the responsible investigator need only apply for renewal of approval using the Approval Renewal Application Form (available from the IRB office or the Office of Research Administration web page) before the expiration of existing approval.

If, in the conduct of research, problems involving risks to human subjects arise which were not foreseen in the approved protocol, the problem must be reported to the Board through the IRB Administrator in the University's Office of Research Administration. In the case of DHHS projects, the IRB Administrator will report such problems to the DHHS (OHPR, The National Institutes of Health, DHHS, Bethesda, Maryland 20892) through the University's Division of Research and Economic Development.

Amendments to Previously Approved Research

Any proposed changes in approved research must be reviewed and approved by the IRB Administrator if the change is non-substantive, or by the IRB if it is a substantive change to the study methodology, prior to implementation to ensure that the modified research continues to meet the criteria for approval, except when it is necessary to implement changes to eliminate apparent immediate hazards to the subjects. In this situation, the changes must be promptly reported to the IRB Administrator.

9. Study Closure

Closure of human subjects research must be reported to the IRB within a reasonable time frame after completion of the research (or a decision that IRB-approved research will not be initiated).

Completion of the research occurs when:

- All research interventions and interactions with subjects have concluded, and
- All access to and use of identifiable research data is complete.