

Institutional Review Board Researcher's Guide

(apropos to the OHRP approved Federalwide Assurance, #00000069, which expires on 01/18/2010)

INTRODUCTION

Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the [Nuremberg Code](#) of 1946, the [Helsinki Declaration](#) of 1964 revised in 1975, 1983, 1989 (prepared by the World Medical Association), the Code for the conduct of social and behavioral research being that of the American Psychological Association in 1973, and in 1974 the Federal Regulations issued by the U.S. Department of Health, Education, and Welfare were adopted .

Based on the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978), the Department of Health and Human Services (HHS) revised and expanded its regulations for the protection of human subjects 45 CFR part 46 in the late 1970's and early 1980's. In 1978, the Commission's report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" was published. It was named the [Belmont Report](#), for the Belmont Conference Center, where the National Commission met when first drafting the report. The Belmont Report explains the unifying ethical principles that form the basis for the National Commission's topic-specific reports and the regulations that incorporate its recommendations. The Belmont Report identifies three fundamental ethical principles for all human subject research – respect for persons, beneficence, and justice. Those principles remain the basis for the HHS human subject protection regulations. It is the designated function of the Institutional Review Board (IRB) to weigh these three principles in their review of research proposals.

University of Maryland Baltimore County, henceforth referred to as UMBC, requires that all proposals involving human participants be reviewed and approved by our Institutional Review Board (IRB) before any such activity begins. Principal investigators, whether they be a faculty member, staff member, graduate student or undergraduate student, have the primary responsibility for the ethical use of humans in a research study. Primary oversight responsibility for the ethical use of humans in a research study rests with the IRB. *Any and all research projects with humans must be reviewed by the IRB regardless of the source of funding.*

Prior to initiating a human subject research protocol or a report to the IRB regarding past, present or future research, an investigator must first determine what type of submission is appropriate. There are several different categories for submissions: *new protocols*, submitted via exempt, expedited or full board review; *renewals* (or continuations) of previously approved protocols. Protocols are approved for a period of five years - a protocol is initially approved for a period of up to 12 months. Four (4) continuations (renewals) may be requested, each for a period of up to 12 additional months. UMBC employs a primary reviewer system for expedited review of new protocols and renewals, where a member of the IRB performs the principal analysis of the protocol and the IRB Chair complete the final review and approval. The Chair evaluates and approves all exemption protocol requests.

Amendments, which are modifications to a currently approved protocol and/or consent form and *closures*, which include the termination of protocol activity are reviewed and approved by the IRB Chair. *Adverse events or unanticipated problems*, which are any events that may cause an adverse effect to a participant, are examined by the committee for appropriate deliberation.

Investigators are encouraged to review all aspects of the Guide prior to completing application forms.

MISSION OF THE IRB

The main mission of the IRB is to see to the appropriate protection of human participants in behavioral (and biomedical) research, according to the regulations established by the Department of Health and Human Services (DHHS) - [Office of Human Research Protections](#) (OHRP), National Institutes of Health (NIH), and State and Local law.

For reference and use in grant and contract applications, UMBC's IRB Federalwide Assurance Number is FWA00000069.

The IRB accomplishes its mission by reviewing each new proposal for human research, noting any significant changes to approved protocols, and reviewing its approval every twelve months or more frequently, depending on the protocol.

Questions the IRB must answer:

The **first question** is: are human subjects involved?

Participants involved in a *research project* means taking part in an activity that is a *systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Systematic investigation refers to an organized, scientific way of collecting information, using a series of questions or observations. Contributing to generalizable knowledge comes from research activities that are designed to contribute to the general body of knowledge.

Participants (or subjects) are living individuals about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. Interaction of any type that elicits a response and that reaction is recorded, through physical or nonphysical activities, constitutes engagement with human beings. *Identifiable* information are data recorded through methods to allow someone to identify the person and the circumstances of the event are such that the person would reasonably assume no recording was taking place. If an investigator is just doing interviews with people, human participants are involved in research

The **second question** is: do the chances of benefit outweigh the risks of harm?

Both benefits and harms are described in these terms:

- accruing to whom? And, to the subject and/or society?
- probability?
- magnitude, or intensity?
- duration?

Benefits should never be overstated or understated, but explained completely to participants. Benefits may be classified as: *direct* (comes from directly participating in the projects), *collateral* (participants may gain knowledge or information of a previously unknown item), or *aspirational* (something that benefits the common good).

Some risks may be perceived as harmful; some as necessary risks of treatment for the subject's medical condition; some as risk of inconvenience; and some as hazards usually associated with the volunteer research subject's lifestyle and/or work. Risks vary by age, gender, ethnicity and environment and are variable by nature, duration, magnitude and probability.

On the basis of the analysis of risk to benefit ratio, the IRB must decide whether the risk is balanced by direct benefit to the individual or to society. If the risk or risks are held not to be balanced, the proposed research study or protocol cannot be approved.

If the risk or risks are deemed acceptable, the **third question** is: is there an acceptable mechanism for obtaining a fully informed and freely given consent from the proposed research participants?

ADVICE TO INVESTIGATORS

An investigator, as a **faculty member, staff member, graduate student or undergraduate student**, planning a new research project involving human participants must complete *UMBC Application for Approval of Use of Human Participants* form, which serves as application for IRB approval. Researchers, whose projects fall within exempt categories, must complete an *Exemption Certificate Application*. No human participants may be involved in any project until the project has been reviewed and approved by the IRB or has been determined to be exempt, and, if required, IRB certification submitted to the appropriate funding source.

General Definitions

Research

"Research" is defined in the Code of Federal Regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

Examples of activities that constitute research include

- o any study intended to result in publication or public presentation
- o any use of an investigational drug or device

An example of an activity that is not research would be any evaluation of an employee, course, program or service where such evaluation is not designed to lead to generalizable knowledge. If an activity does not involve research, it does not require approval or review by the IRB.

General examples of research conducted at UMBC, to help plan a study, as well as additional illustrations of what projects might not require IRB review may be found [here](#).

If you have any doubt as to whether an activity constitutes research, please consult with the Human and Animal Research Protections Office [staff](#).

Human Participants

Human participants or "subjects" are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".

Some examples of participants include:

- o individuals who are asked to complete questionnaires, participate in interviews, or whose behavior is observed in daily activities
- o participants in pilot studies in which there is more than minimal risk to subjects, or when the data will be used for a research publication
- o oral history interviewees whose subjective perceptions are studied
- o students and teachers observed in the classroom for the study of various teaching

methods or development of curricula

Designing a Study

In designing the study, the investigators should take into consideration the three underlying ethical principles for conducting research with human participants: autonomy; beneficence; and justice.

Autonomy

Autonomy means that each person should be given the respect, time, and opportunity necessary to make his or her own decisions. Prospective participants must be given the information they will need to decide to enter a study or not to participate. There should not be pressure to participate. The principle of autonomy requires that extra protection be given to potentially vulnerable populations such as children, the elderly, the mentally ill, or prisoners. Individuals in these groups may be incapable of understanding information that would enable them to make an informed decision about study participation.

Beneficence

Beneficence obligates the researcher to secure the well-being of all study participants. It is the responsibility of the investigator to protect participants from harm, as well as ensure that they experience the possible benefits of involvement. In some cases, benefit may not be to the participant but to society as a whole. Balancing risks and benefits is an important consideration. The key, according to the Belmont Report on the protection of human participants, is to "maximize possible benefits and minimize possible harms."

Justice

The ethical considerations of risks versus benefits raise the question of justice. Who should bear the risk of a study, who is equal and who is not, and who should receive its benefits? The concept of justice may be questioned when we attempt to decide who will be given an opportunity to participate and who (and for what reason) will be excluded. Are some classes or persons being selected simply because of their availability, their compromised position, or their manipulability while others are not?

INVESTIGATOR'S RESPONSIBILITIES

The IRB requires that all investigators (**faculty members, staff members, graduate students or undergraduate students**) comply with both internal and federal regulations regarding the protection of human subjects and the appropriate administration of protocol activities. Researchers, in turn, have the responsibility of staying abreast of policies to remain within compliance. Failure to do so will result in the investigator losing their capability to perform as the individual responsible the administration of the research protocol.

Investigators are responsible for:

- 1) Completing the [UMBC Collaborative Institutional Training Initiative \(CITI\)](#) program prior to initiating a new protocol.
- 2) Ensuring that all research involving human subjects is submitted to and approved by the IRB prior to initiation of the research. Each investigator Investigators has the primary responsibility for protecting the rights and welfare of human research subjects. In addition, they are expected to be

knowledgeable about the requirements of the Federal regulations and institutional policies and procedures for the protection of human subjects.

- 3) Complying with all IRB policies, decisions, conditions, and requirements. Investigators are responsible for ensuring that the research is implemented as specified in the approved IRB protocol.
- 4) Obtaining and documenting informed consent for each participant and providing a copy of the IRB approved consent form to each subject, unless the IRB has specifically waived this requirement.
- 5) Ensuring that assent from research participants who are minors (18 years of age and under) is obtained and documented
- 6) Reporting progress of approved research to the IRB, as often as and in the manner prescribed but no less than once per year.
- 7) Promptly submitting to the IRB any modifications to a protocol or consent form of an approved protocol.
- 8) Promptly reporting any injuries, adverse events or other unanticipated problems involving risks to participants.
- 9) Maintaining a protocol file that includes all correspondence between the IRB and principal investigator and retaining copies of signed consent forms.

About protocol files

The principal investigator must maintain a protocol file, which must include:

- a. All correspondence between the investigator and the IRB as well as any communications regarding the study from a sponsor.
- b. Copies of the signed Consent Form obtained from all participants or information as to where these documents can be found.
- c. Any data derived from the study.
- d. Progress reports
- e. Reports of all adverse incidents and any follow-up to adverse incidents
- f. Current contact point for the investigator (address and telephone number) should the investigator no longer be associated with UMBC.

If a student is the lead investigator, the faculty member retains ultimate responsibility for the storage and accessibility of the protocol file. At a minimum, the file must contain a copy of the used approved consent forms, data and correspondence. This file will act as the investigator's documentation regarding the proper performance of the study. Investigators should be aware this file will be randomly audited on a semi-annual basis by the IRB. The purpose of this audit is to provide internal procedural monitoring to ensure compliance with federal human subject protection regulation. Additionally, it provides a cooperative forum to educate the investigator in correcting problems and to solicit suggestions in improving the IRB process.

The investigator must maintain for five (5) years following protocol closure, three (3) years for protocols involving minor subjects, whichever is longer, copies of data files, consent forms, progress reports and other items used in the course of the investigator's research while employed at UMBC. If an investigator leaves UMBC prior to this five (5) year period, he/she must notify the

IRB in writing of the individual taking over the responsibility for these records (e.g., Department Director, Human and Animal Research Protections Office). All files must be kept in a secure location.

IRB MEMBERSHIP

Authority

The IRB is empowered by federal regulation ([Title 45 Part 46](#) of the Code of Federal Regulations) via the OHRP approved [Federalwide Assurance](#) to review and approve, require modifications in (to secure approval), or disapprove any research activities dealing with human subjects. The responsibility for appointing and maintaining the IRB rests with the Vice President for Research or his/her designee.

Appointment

[Federal Policy §46.107](#) provides that IRBs must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. Members of the UMBC IRB represent the background, expertise and scope of social and behavioral science required by DHHS. In addition, the UMBC IRB have a person not affiliated with UMBC, but participates as a full voting member. Generally, appointments are for a three year renewable term; student members are appointed for a one year, non-renewable term.

The current IRB membership roster for AY 2008-2009 is as follows:

Name	Department
Susan Sonnenschein, IRB Chair	Psychology
Lowell Groninger	Psychology
Ashley Corbin	(non-affiliated)
Thomas Robinson	Africana Studies
Henry Emurian, Vice Chair	Information Systems
John Stolle-McAllister	Modern Languages and Linguistics
Sarah Chard	Sociology/Anthropology
Gina Fitzmaurice	Undergraduate Student, Health Administration & Policy Program
Saratupa Joardar	Graduate Student, Modern Languages and Linguistics

Joseph Clift	(non-affiliated)
--------------	------------------

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that routinely available on the IRB. However, these "ad hoc" individuals may not vote with the IRB.

IRB members cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interest. Where a member has a conflicting interest, he or she are present only to provide information requested by the IRB. That member is then absent from the meeting room during the discussion and voting phases of the review and approval process.

Additional information about conflict of interest is available for IRB members from:

[UMBC Policy on Individual Conflicts of Interest in Research & Product Development](#)

[NIH Publication: Financial Conflict of Interest – Objectivity in Research](#)

[Financial Conflicts of Interest in Academic Medicine](#)

Support

The IRB is supported by the UMBC [Vice President for Research](#).

IRB MEETINGS

The UMBC Institutional Review Board meets in MP 322 every sixty (60) days to review human subjects protocols. Full committee reviews of protocols are performed at each of the scheduled meetings.

The meeting schedule for the 2008-09 academic year is as follows:

October 06, 2008; Full Board Review applications due by **September 08, 2008**

December 01, 2008; Full Board Review applications due by **November 03, 2008**

February 02, 2009; Full Board Review applications due by **January 05, 2009**

April 06, 2009; Full Board Review applications due by **March 02, 2009**

June 01, 2009; Full Board Review applications due by **May 04, 2009**

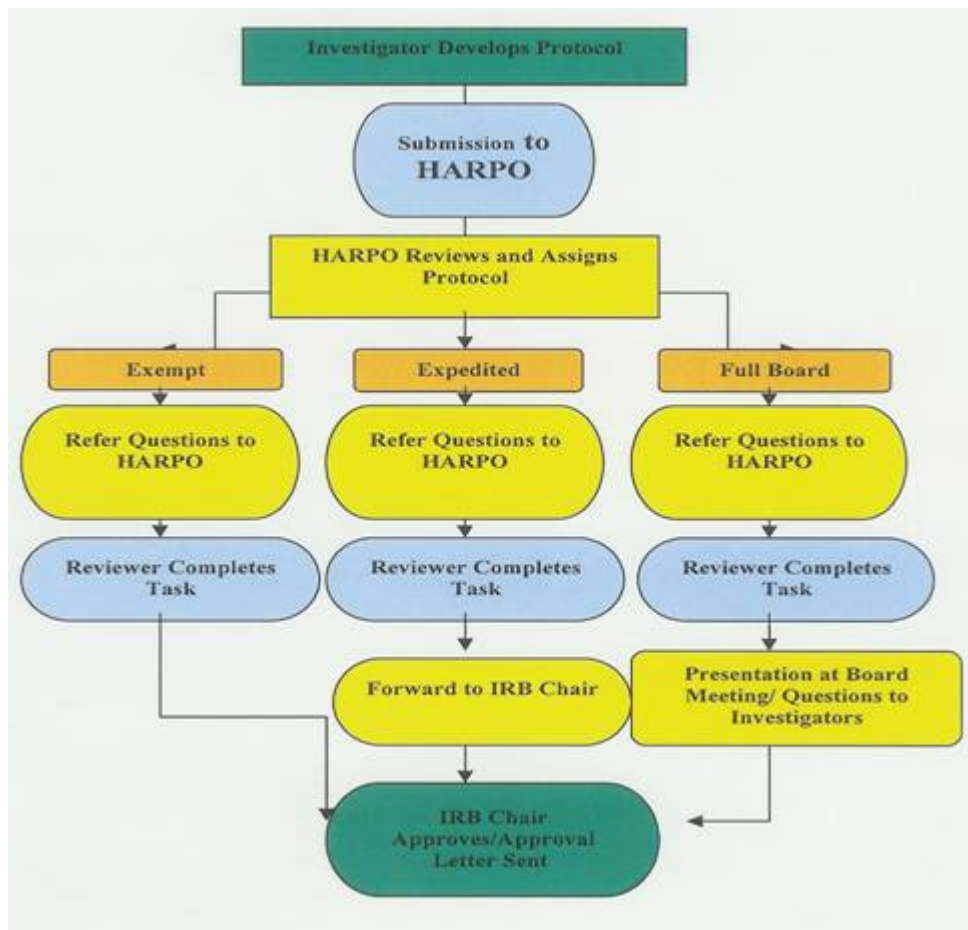
The review of all human use research takes place at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

In order for a protocol to be reviewed and approved by the IRB, it must meet all the criteria for submission outlined in this guide. If the protocol does not meet the requirements for processing, the PI will be notified.

Review Procedures

Below is a general diagram of the protocol review process, from submission to approval. The IRB Chair and individual Board members perform the "mechanics" of the review, while the Human and Animal Research Protections Office handle communication and correspondence between the IRB and the investigator.

The Primary Reviewer's identity is not revealed to the investigator. At the discretion of the reviewer, he/she may elect to have the Human and Animal Research Protections Office contact the principal investigator for further clarification on a protocol issue. The principal investigator is to respond, in writing, to the reviewer's questions and submit to the Human and Animal Research Protections Office. These responses will be forwarded to the Primary Reviewer and to the IRB members.



TYPES OF APPROVAL

Initial Approval

IRB approval is granted when all requirements are met based on the federal regulations and UMBC IRB policies. Upon approval, the PI is sent written notification with the IRB approval number and annual review date. The written notification of approval will be provided directly to the faculty advisor if the principal investigator is a student. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Continuing Review (Renewals)

Federal policy requires all studies approved in an expedited category or by full board review be renewed at minimum annually. Annual renewal is required until all the data has been analyzed and all activity, including participant contact, related to the project has ceased.

Modifications

Once a protocol has received approval by the IRB, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation. Per federal regulations, any desired modification in an approved research protocol must receive approval from the IRB.

WHAT REQUIRES IRB REVIEW?

What kind of projects may not meet the Federal definition of “Research” and may not need to be reviewed by the IRB?

"Research" is defined in the Code of Federal Regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". Certain activities have the characteristics of research but do not meet the regulatory definition of research needing IRB review.

Contact the Human and Animal Research Protections Office at 5-2737 or HARPO@umbc.edu with questions of clarification. Remember, the IRB has the final say in what research must be reviewed.

Examples of research that may not require IRB review:

1. Activities with no hypothesis-driven methodologies and no research protocol, where the anticipated result or product is the publication of an article in a newspaper or magazine
2. Data collection for internal departmental, school, or other University administrative purposes.
Examples: teaching evaluations, "customer service" surveys.
3. Surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni, as long as the privacy of the participants is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. If, at a future date, an opportunity arose to contribute previously collected survey data to a new project producing generalizable knowledge, an application for IRB review would be required before the data could be released to the new project. See the [QI/QA algorithm](#) for additional guidance.

4. Fact-collecting interviews of individuals where questions focus on things, products, or policies, rather than on people or their opinions. Example: canvassing librarians about inter-library loan policies or rising journal costs
5. Course-related activities designed specifically for educational or teaching purposes, where data is collected from human participants as part of a class exercise or assignment. The individual data that will be collected and the project product must not be disseminated outside the institution. The course instructor is responsible for ensuring that ethical guidelines are followed and that such projects involve minimal risk and could have otherwise qualified for exempt or expedited review. In these cases, consent forms must clearly state that the data are collected solely for pedagogical reasons and not for actual research purposes. Example: instruction on research method
6. Searches of existing literature.
7. Research involving a living individual, such as a biography, that is not generalizable beyond that individual.
8. Procedures carried out under independent contract for an external agency. Generally, program evaluations not requiring human subjects review involve data internally collected and analyzed for the normal course of business. The evaluation goals range from simple descriptive statistics to qualitative information, and examples include program enrollment data, constituent demographics, and outcome analyses. Therefore, irrespective of human subject involvement, these program evaluations remain internal and thus do not contribute to generalizable knowledge.

Examples of human specimen research that may not require IRB review:

1. Use of biological or pathological specimens and/or data and that neither the investigator nor collaborators can identify the subjects from whom the specimens and/or data were obtained either directly or indirectly through coding systems.
2. Research involving only coded private information/data or coded specimens. Use of this data and specimens is not considered research provided these conditions are **both** met:
 - the private information/data or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**
 - the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - the key to decipher the code is destroyed before the research begins;
 - the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;
 - there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or

- there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

Program evaluations whose results will be published in scholarly journals will require IRB approval. The assumption being that publishing the findings generalizes the data. The results of the evaluation may impact upon the replication of other programs or services and the population at large or public policy should be reviewed and monitored. Finally, funding source may impact a program evaluation's human subject's requirements. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies.

WHO ARE PARTICIPANTS?

Participants (or subjects) are living individuals about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. *Interaction* of any type that elicits a response and that reaction is recorded, through physical or nonphysical activities, constitutes engagement with human beings. *Identifiable information* are data recorded through methods to allow someone to identify the person and the circumstances of the event are such that the person would reasonably assume no recording was taking place.

CHILDREN

Children are considered a vulnerable research population because their intellectual and emotional capacities are limited and they are legally incompetent to give valid consent. Special procedures and considerations are, therefore, required by the Federal regulations for the review of research involving children. Whenever feasible, appropriate studies should be conducted on animals, adults and older children before young children are involved as research participants. In reviewing protocols, the IRB will consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children and the permission of parents or legal guardians.

Investigators, when developing protocols, must ensure the informed consent process is clear that there is no prospect of benefit to the individual participant, and that the assent and permission are voluntary and uncoerced with no implication of obligation.

Who is a child according to federal regulations?

"Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd>). In most cases, these are individuals under the age of 21 years. However, in the state of Maryland, individuals are adults and of legal age (released from parental authority), when one attains the age of 18 years. Minors are those individuals who have not attained the age of eighteen years (source: http://mlis.state.md.us/cgi-win/web_statutes.exe - section § 24).

Obtaining consent and assent for participation

In almost all cases, written consent from a parent or legal guardian must be obtained if the research involves children under the age of 18. In cases where child abuse is an issue, the requirement for parental consent can be waived.

Documentation of assent is required for participants between the ages 7 and 18 years of age unless the participant is incapable, either mentally or emotionally, of being reasonably consulted about participating. The assent form, submitted to the IRB for review, should include a simplified version of the elements of informed consent, such as an explanation, at a level appropriate to the child's age, maturity and condition, of the procedure(s) to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

(NOTE: Participants under the age of 18 will need to complete an Assent form; a separate parental consent form is required for these participants providing parental permission to participate)

Exempt research with minor children (under age of 18)

Research with children is eligible for exemption from IRB review involving these situations: 1) normal educational practices in commonly accepted educational institutions, 2) educational testing, and 3) observation in public settings. These activities fall under exemption categories (1) and (2), with the following provisions:

[46.101\(b\)\(1\)](#): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. All data collected must be compiled as "groups of students" with no possible way to identify individuals, or compromise privacy or confidentiality.

[46.101\(b\)\(2\)](#): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) also applies to children. Information must be obtained and recorded in such a way, that subjects cannot be identified.

Research and procedure involving surveys (such as longitudinal studies), interview procedures (of ethnographic nature) or observations of public behavior where the investigators participate in the activities being observed does NOT meet exemption classification. In these cases, investigators are involved in an intervention and/or interaction where privacy may be compromised.

Waiver of Parental/Guardian Permission

By regulatory definition, "children" are persons who have not attained the legal age for consent to treatments, procedures, or other activities involved in research. Since children are considered a vulnerable population, the IRB imposes additional protections on research involving children, in accordance with the [45 CFR Part 46, Subpart D](#). This includes the investigator obtaining the permission of parents or guardian through the consent process and of the assent of the child, and the IRB being able to make certain findings based on the level of risk and benefit of the research. Consent from a parent or guardian must always be an affirmative agreement to participate or to give permission for one's child to participate in research.

The IRB may waive parental or guardian permission if:

- the regular conditions for waiver of consent are met (see 45 CFR [46.116\(c\)](#) or [46.117\(d\)](#)); or
- the study focuses on a condition for which parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted, e.g. is of such private and sensitive nature that it is not reasonable to require permission, (for

example, adolescents in studies concerning treatment of sexually transmitted disease);
or

- a subject population for which parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted, e.g. is such that parental permission is not a reasonable requirement to protect the participants, (for example abused or neglected children). (45 CFR [46.408](#))

Research that does not pose greater than the minimal risk

A waiver of the requirement for parental or guardian permission may be requested by the researcher in studies that do not pose greater than minimal risks to the subjects. In such research, prior parental notification could then be used as one mechanism for meeting the requirement in [46.408\(c\)](#) that an "appropriate mechanism for protecting the children who participate as subjects in research is substituted." Researchers will be required to provide a detailed plan for fully informing parents/guardians about the potential study and document that the research meets the criteria found in [46.116\(d\)](#). A letter or packet of information sent home to parents or guardians with information about the study (for example, with students as part of regular school mailings) would satisfy parental notification. The IRB may accept an alternative mechanism to protect the child participants (i.e., appoint a qualified child advocate). In accordance with the federal regulations, the IRB requires that the investigator obtain the assent of the children, if the children are capable of providing assent, and it is not waived. The IRB also needs to know how the affirmative assent of the child will be documented, e.g., signature on assent forms, documented by the investigator, or other.

In certain situations, studies that may have a risk/benefit ratio where the benefit is high and will make a positive impact on the life and welfare of the children population involved. In these cases, researchers may be interacting with subject groups where parents or guardians have a lower response rate and do not send in consent forms, even after repeated attempts. In other extreme cases, a parent or guardian may not have the capability or knowledge to decide what is in a child's best interests.

Classroom or school based research

Research is ordinarily NOT suitable for a waiver of permission if it involves any of the following issues:

- parental political affiliations or beliefs
- mental or psychological problems
- sexual behavior or attitudes
- illegal, antisocial, or self-incriminating behavior
- appraisals of other individuals with whom the minor has a familial relationship
- relationships legally recognized as privileged (lawyers, doctors, clergy), or
- religious affiliations or beliefs.

More than minimal risk research

One cannot obtain a waiver of parental consent for research that involves more than minimal risk unless the research involves issues of child abuse or neglect or other situations where obtaining parental permission might increase the risks to the child participants. In such cases parental consent may be waived. However, the investigator must supply an appropriate mechanism and justification for obtaining consent from someone serving as an advocate for the child.

In situations where the protocol involves more than minimal risk, parental consent alone may NOT be sufficient. A recent ruling by the Maryland state appeals court (downloadable in .pdf format, [Grimes v. Kennedy Krieger - 366 Md. 29](#)) affects how researchers in Maryland may conduct research with children that involves more than minimal risk. Although this ruling pertained to medical research, UMBC investigators, who plan to involve children in more than minimal risk studies, must carefully design protocols that will sufficiently provide protections from potential research harms. That is, investigators cannot use a placebo control group if a more effective intervention is available. Protocol submissions will require full board review.

STUDENTS

Every semester studies on human behavior are conducted across the campus by student and faculty researchers. Participants for such studies may sometimes be drawn from subject pools, undergraduate students enrolled in particular departmental courses. The Institutional Review Board reviews and approves all research requesting subject pool participation. This document describes policy and procedures affecting participants recruited from classes at UMBC.

Students enrolled in a course may be asked to participate in ongoing research because such participation is deemed a valuable educational experience for the student and/or to aid in the pursuit of knowledge by investigators. Regardless of why students enrolled in courses are asked to participate in a study, student participation must be completely voluntary.

There are two main reasons that students enrolled in courses may be asked to participate in research. One, an instructor in a class may be interested in investigating different pedagogical tools or techniques. For example, an instructor may investigate which style of lab is more beneficial for students. All students enrolled in a course will be placed in one of two lab sections and their performance on a final exam will be compared. Students need to be informed about the nature of the research project including that their scores on an exam will be used as data for the study. As enrollment in research is voluntary, students have a choice of whether or not to allow their scores to be used in the research project. Students do not have a choice, however, about the pedagogy of the course or whether they need to take the final. By enrolling in the course, the students have agreed to abide by the class syllabus and rule.

A second way that students enrolled in courses are used in research projects is through the use of a participant pool. For example, Psychology 100 allows students to earn extra credit for participating in approved research studies. Such participation is deemed an appropriate learning tool as it lets students learn about the research process (in addition to allowing researchers assess to participants). Such participation is voluntary, however. Students cannot be required to participate in studies.

Investigators choosing to recruit participants from class subject pools must abide by the general procedures governing research participation. The incentive offered for participation must be commensurate with what participants are asked to do. Note that typically students are offered some form of extra credit. However, it is up to the instructor of a course to determine whether to allow extra credit. Reimbursement for participation must not jeopardize a participant's confidentiality or anonymity. Students under the age of 18 years, must have parental consent for their participation.

Each experimenter must provide, in writing, a brief but informative description of the experimental procedure, the expected duration of the student's participation, a description of any reasonably foreseeable risks or discomforts to the subject, the foreseeable benefits of participation, as well as assurance that the student is free to withdraw from the experiment at any time without penalty. The student is usually required to sign this informed consent form prior to participation in any study. All participants must be given the most complete debriefing possible at the end of the study. In cases, where full disclosure is not appropriate immediately after a student participates, students have the right to receive such disclosure at a later date.

Each department should develop their own policies and procedures for participation in student subject pools. Students should check with their instructors about the details of such procedures (e.g., is there a subject pool for a specific course, sign-up procedures, how to document one's participation)

Participant Rights and Responsibilities

- 1) Instructors may not require students enrolled in their class to participate in their research.
- 2) Students who volunteer to participate in a study are entitled to receive as much information as a participant would reasonably want to know to make an informed decision about participation before signing up. In the unlikely case that the explanation must be postponed until the completion of the study, participants should be sent a summary of the study at the end of the semester.
- 3) Students may withdraw from participation at any time without penalty. Withdrawing students do not receive credit for participation.
- 4) If a student believes that he or she has been treated unfairly or harmed in a study, the student should contact either (1) the instructor, (2) the faculty member supervising the study; (3) the chair of the department; (4) or the Chair of the UMBC IRB.

DECISIONALLY CHALLENGED

Mental disorders have in recent years been the focus of research studies that have produced not only important and clinically relevant scientific findings but also a certain amount of public controversy, governmental sanctions, and even lawsuits. Although existing federal regulations for research involving human subjects have provided special protections for certain populations that are regarded as particularly vulnerable, persons with mental disorders who may have impaired capacity to make decisions, and therefore to give voluntary informed consent, have not received any such special protections. The [National Bioethics Advisory Commission](#) states that: 1) research may be conducted or funded if it does not involve greater than minimal risk; 2) interventions or procedures that involve greater than minimal risk but have prospect of direct benefit to the subjects may be conducted if the risk is justified by the intended benefit to the subjects and the anticipated benefit is at least as favorable to the subjects; and 3) interventions or procedures that present a minor increase over minimal risk and do not present the prospect of direct benefit to the subjects but are likely to yield generalizable knowledge about the subject's condition or disorder may be conducted or funded if the subject's experiences with intervention or procedure are reasonably commensurate with those inherent in their actual or expected medical, psychological, social, or educational situations. Above all, a legally authorized representative has to provide permission for the subject to participate in the research.

ELDERLY

Elderly persons are commonly regarded as vulnerable. With advancing age, people are increasingly likely to acquire attributes that define them as vulnerable. They may, for example, be institutionalized or develop varying degrees of dementia. If and when they acquire such vulnerability-defining attributes, and not before, it is appropriate to consider them vulnerable and to treat them accordingly.

THIRD PARTIES

Participants who provide information about other people who are not directly interviewed are known as "third parties". A research project should be assessed for the likelihood that third parties could be harmed. If the project is low risk then no special oversight is required. If the data are stripped of identifiable private information then no "human subjects" are involved. The IRB, though, makes the final determination.

All project information should be kept confidential; the level of confidentiality (applicable to all identified persons, not just interviewed subjects in the research) should be commensurate with the level of risk. Federal regulations do not automatically mandate informed consent from third parties. If the potential risk is serious and not ameliorated by confidentiality procedures, then consent is necessary. Additional information may be found from a report from the [National Human Research Protections Advisory Committee](#).

EMPLOYEES

The enrollment of employees of UMBC raises essentially the same issues as detailed above for students. The IRB requires adequate justification for recruitment of employees of UMBC or any affiliate as normal controls in any protocol. Investigators proposing the use of employees of UMBC should clearly address the use of employees in the Consent Form.

SELF EXPERIMENTATION

Faculty and students who wish to become involved as experimental participants in the development of their research should consider themselves to be "human subjects". Currently, Federal regulatory documents make no distinctions between whether an investigator uses him/herself as a research subject or whether the investigator recruits others to participate in a research activity as a research subject.

The IRB requires notification of any intent of an investigator to involve him/herself as a research subject prior to the research activity being initiated. This requirement has been made for the following reasons:

a. To protect the prospective subject from taking unwarranted risks in the excitement of generating new knowledge. Under these circumstances, investigators are enthused about the prospect of new knowledge, and concern for any associated risk may be minimized or escape attention.

b. To protect the process of human investigation in an era when the process has articulate critics. While the recommendation for review may be viewed as a limitation of personal freedom, it is a price currently endured to protect clinical investigation. If there were an accident leading to death or a permanent injury, a number of issues regarding insurance coverage, benefits, etc., would have to be addressed.

PREGNANT WOMEN

Regulations covering pregnant women, fetuses, etc. are in [45 CFR Subpart B](#). Typically, UMBC does not conduct this type of research but if such a protocol is submitted, appropriate information on risks to the fetus is to be included in the consent form.

PRISONERS

Regulations covering prisoners as participants are in [45 CFR Subpart C](#). Any researcher proposing to enroll prisoners should first submit approvals from appropriate prison authorities before requesting IRB review. If these approvals are submitted, then an ad hoc representative of prisoners will need to be appointed to the IRB by the Institutional Official and NIH must be informed. Appropriate representatives might be a former prisoner, etc. The principal investigator must provide a rationale for using prisoners and a description of safeguards of prisoner rights to be followed.

TYPES OF RESEARCH

STUDENT INITIATED RESEARCH

Research, as defined in CFR Title 45, Part 46, is a systematic investigation (an organized, scientific way of collecting information, using a series of questions or observations) designed to develop or contribute to generalizable knowledge. Data is collected from a "human subject", who is a living individual about whom an investigator (a faculty member or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

These definitions are important to remember when students (undergraduate and/or graduate) are contemplating to conduct independent class projects, senior theses, masters projects and doctoral dissertations.

Faculty advisors play an important role in the student's design and development of human participant research project and are ultimately responsible for the protection of the subjects, even if the student is the primary researcher and actually directs the project. Advisers shoulder the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

Independent Research

Student investigators performing independent research or conducting senior theses, master's projects and doctoral dissertation research are required, as are faculty investigators, to follow the appropriate application review and approval process before conducting an independent research project. Consult the submission procedures and forward to your faculty advisor for review and signature before the electronic submission process. It is expected the faculty advisor will review the application before submission to the IRB. His/her signature on the application indicates the appropriate review has taken place.

Research Within a Faculty Advisor's Approved Protocol

Student researchers may wish to carry out research projects or studies while using data collected on a faculty advisor's IRB approved protocol. The pursuit of a thesis or dissertation that falls within the purview of a previously approved IRB protocol is permissible, provided the level of risk

does not change, no additional benefits are realized by participants, and the scope of the student's research project does not significantly differ from the parent protocol.

The IRB does not want to burden the student researcher or faculty advisor with completing a full application for review and approval, but will want to track these projects to ensure the proper ethical oversight is performed. Therefore, faculty advisors and student researchers will complete a two step process:

Faculty advisors will notify the IRB by using the [Protocol Modification Request form](#) that a students will undertake a separate or new line of inquiry while working under the advisor's approved project. This form may be submitted at any time during the period of IRB approval. Moreover, a faculty may inform the IRB about these projects using the [Annual Continuation Report form](#) if the student project is planned for the next approval period.

Student researchers will inform the IRB of their prospective projects using the [Thesis, Masters or Dissertation Research Notification form](#), a short descriptive form that explains the purpose of the proposed study, the use of proposed procedures and measures, how data will be collected, any changes to risks or benefits and if additional consent of participants is required. This form will be electronically submitted to irbsubmissions@umbc.edu with a copy of the completed application signature page, signed by the investigator(s) scanned and sent to irbsubmissions@umbc.edu or faxed to the Human and Animal Protections Research Office at (410) 455-3868. Review of these notification forms will not be processed until this face page is received.

USE OF HUMAN TISSUES AND SAMPLES

A 'human subject' is a living individual about whom an investigator obtains either data through intervention or interaction with the individual or identifiable private information. Exemption category # 4 ([§46.101\(b\)4](#)) may be used for research projects 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

Legal obligations to protect human subjects apply, for example, to research that use—

- a) Bodily materials, such as cell lines, blood or urine, tissues, organs, hair or nail clippings, even if you did not collect these materials
- b) Residual diagnostic specimens, including specimens obtained for routine patient care and autopsies that would have been discarded if not used for research.
- c) Private information, such as medical information that can be readily identified with individuals, even if the information was not specifically collected for the study in question. Research on cell lines or DNA samples that can be associated with individual's falls into this category.

What is meant by "existing" data or specimens?

Exemption #4 applies to retrospective studies of specimens and/or data that have already been collected. The materials must be "on the shelf" (or in the freezer) at the time the protocol is submitted to the IRB. Research that involves the ongoing collection of specimens and/or data does not meet the criteria for Exemption #4.

What is meant by "publicly available sources"?

This language in the regulation was intended to apply to public sources of data, such as census data. Its meaning with respect to human tissue specimens is widely debated. Although there are organizations that make human cells and tissues broadly accessible to the research community, these materials are not usually available to the public at large and are not generally considered to be publicly available.

What is meant by "identifiers linked to the subjects"?

Identifiers, such as names, social security numbers, medical record numbers, or pathology accession numbers, or other codes that permit specimens to be linked to living individuals and perhaps also to associated medical information.

Biological or pathological specimens qualify for exempt review (under Exemption category # 4 [§46.101\(b\)4](#) only if:

- Investigators do not receive or have access to existing individually identifiable private information or identifiable specimens from living individuals (e.g., pathology or medical records).

If one retains or can access any identifiers, the research project is not exempt under Exemption 4 and must be submitted for **expedited or full board review**.

See the [Protocol Development](#) page for examples of research with biological or pathological specimens that do not require IRB oversight.

Researcher's are advised to review the following guidance from The Office for Human Research Protections coded private information or specimens " **Guidance on Research Involving Coded Private Information or Biological Specimens at** <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>."

IRB protocols which involve the use of human biological specimens may need to address the following in the human participants use protocol form:

1. The potential hazards of working with the agent (i.e. sharps, splashes, ingestion)
2. The [appropriate risk group and biosafety level containment level](#) for work with the hazard
3. The use of personal protective equipment (PPE) requirements for all procedures involved (i.e. cleaning up spills)
4. An explanation of what engineering controls are necessary to protect workers from potentially hazardous aerosols.
5. Training of all personnel who handle the agent or work with human tissues and samples
6. Exposure follow-up (Occupational Health and Safety)

Additional information and regulatory guidance and proper biohazardous materials waste disposal procedures may be found on the UMBC Biosafety Program web site, <http://www.umbc.edu/ibc/>

PILOT STUDIES AND DATA

The purpose of a pilot study is to evaluate the feasibility of a more exhaustive study and to serve as a model for the larger, more exhaustive scope of the research. In other words, pilot data is used to determine if a proposed study has the sufficient power to produce scientifically valid results. Some of the purposes for using a pilot study include the testing of a survey or questionnaire (to identify issues with wording or confusion with terms), identify potential issues with subject recruitment and participation, or to estimate statistical variations for the ultimate use and calculation of data.

IRB's need to review requests for such studies to determine if the risk/benefit ratio is acceptable. This will provide the Board an opportunity to comment on the ethical considerations of the design. Results from pilot studies may be used, and pooled, with the larger sample, provided the population remains the same and survey methods and instruments **do not** substantively change.

Pilot studies must be reviewed by the UMBC IRB before they are initiated. Such studies are generally approved for **up to one (1) year**. Following successful completion of pilot data collection, a closure report must be submitted to the IRB prior to initiation of a larger scale study, for which the pilot data was collected.

Additional information about the design of pilot studies and the difference between pilot and exploratory studies may be found Steve Simon's web site, via Children's Mercy Hospital, Office of Medical Research, at <http://www.childrens-mercy.org/stats/plan/pilot.asp>.

EDUCATION DATA

Investigators anticipating using student education records should be aware of the regulations promulgated in The Family Educational Rights and Privacy Act (FERPA) ([20 U.S.C. § 1232g; 34 CFR Part 99](#)). In essence, FERPA is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students." Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records.

Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):

- School officials with legitimate educational interest
- Other schools to which a student is transferring
- Specified officials for audit or evaluation purposes
- Appropriate parties in connection with financial aid to a student
- Organizations conducting certain studies for or on behalf of the school

- Accrediting organizations
- To comply with a judicial order or lawfully issued subpoena
- Appropriate officials in cases of health and safety emergencies
- State and local authorities, within a juvenile justice system, pursuant to specific State law.

PRE-EXISTING DATA

What is pre-existing data and when such data may fall within the exempt category of review ([subcategory 4](#))?

Existing or Archival Data

In many areas of the social sciences, one of the most commonly used methods of research is secondary analysis of publicly available files of data collected from surveys. One of the main sources of such data is the federal government (e.g., Bureau of Labor Statistics). Increasingly, federal agencies require that social science investigators make data collected with assistance of federal funds publicly available. In addition, social science professional organizations and journals are establishing the norm that investigators make data sets used for the production of published scholarly papers accessible in public use data files to encourage scholarly replication of research.

What is "existing" data?

The term "existing data" applies to studies involving already collected data where data must be "on the shelf" when the protocol is initiated.

Collection of this data must have been completed prior to the time of application to the IRB. Researchers should not collect the data first and then apply for IRB approval to use them.

Some researchers mistakenly believe that secondary data analyses using existing data to address new research questions are always exempt. [Exemption #4](#) **does not** apply to existing data as long as participants can be identified.

What is meant by "identifiers linked to the subjects"?

Identifiers such as names, Social Security numbers, medical record numbers, and code numbers permit data to be linked to individual people and perhaps also to associated medical, financial, or employment information.

What is meant by "publicly available sources"?

This refers to public sources of data, such as telephone books and public records. Data obtained from data banks, archives, or organizations that make data sets broadly accessible at a reasonable cost to the research community are also considered publicly available. Although there are organizations that make data sets broadly accessible at reasonable cost to the research community, these materials are not usually available to the public at large. Examples of these data sets, where researchers must register to obtain data, include the Inter-University Consortium for Political and Social Research (ICPSR), the U.S. Bureau of the Census, the National Center for Health Statistics and National Election Studies. If data are obtained from any of these sources, a researcher should not assume that the source meets the definition of "publicly available."

How is “data recorded by the investigator”?

Data recorded by the investigator are those data which are transferred from the existing records (i.e. existing datasets from faculty research) to the new research records by the investigator or another member of the research team. Members of the research team may very well look at identifiable data while it remains where it is usually housed, so long as no identifiable information (names, ssn#s, internal id#s) becomes part of the research records, whether written, photographed, audio recorded, or etc. If the data are provided to the research team by a third party, the data must be completely deidentified at the moment of receipt.

Audio/videotapes are considered identifiable even if they have not been labeled with codes or identifiers.

Summary

Research using existing data is **exempt** under [subcategory 4](#) if the data were collected for other reasons other than the research study and are already collected prior to the proposed research study and:

the data come from sources that are publicly available

OR

the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

All other research with existing or archival data would require expedited or full Board review.

Examples of these projects include:

Privately available AND coded data when the investigator and data provider have not established a formal agreement prohibiting the release of identifiers

Privately available data that the investigator will receive in an identifiable format or that will remain identifiable in the research records.

Research using identifiable, sensitive information (e.g. info that reasonable persons would not want disclosed)

Research using sensitive information (e.g., information that reasonable persons would not want disclosed) that is identifiable is not exempt, even when it is publicly available. Research is exempt if it is publicly available and sensitive, as long as it is deidentified and uncoded.

Research that involves combining de identified data sets in a way that may make some data individually identifiable. Research that includes combining more than one data set in a way that may make some data individually identifiable is not exempt under this guidance.

COLLABORATIVE RESEARCH

Collaborating Individual Investigators

At UMBC, the IRB requires that all human participant research conducted by anyone affiliated with the University (faculty, staff, graduate students, undergraduate students) be reviewed and approved by the IRB prior to the start of research. This procedure is applicable regardless of the source of funding. Faculty must take an active role in ensuring that research projects for student theses and doctoral dissertations are conducted in accordance with the IRB's requirements. In these projects, faculty members are considered to be the "investigator of record" even if the student is conducting the study.

Investigators from institutions with a Federalwide Assurance

If a study is being conducted at multiple sites, and IRB approval is needed from all of the institutions "engaged" in research, one institution may act as the "IRB of record". This institution would assume the responsibility of the studies conducted at these multiple sites.

If the cooperative site(s) has its own IRB, the UMBC's IRB preference is that each site be responsible for reviewing the research activities to be conducted at the respective site. The UMBC investigator should obtain a copy of the other institution's IRB approval letter and submit that with the IRB application (or make arrangements to do so when the documents become available).

If UMBC is to be the "IRB of record", the multiple site review arrangement is managed by using an IRB Authorization Agreement. The agreement, documented in writing, must be kept on file at both organizations and must be available for review by OHRP upon request. Each participating institution, however, is responsible for safeguarding the rights and welfare of human participants and for complying with all regulations.

An IRB Authorization Agreement typically describes the role and authority of the IRB(s) involved in the study, the responsibilities of the investigator's regarding human subjects protection education, training, policies, and reporting, the term of the agreement and the number of protocols to be reviewed.

UMBC may also agree to defer responsibility for IRB review, via an IRB Authorization Agreement, to a non-UMBC IRB (who must have an approved Federalwide Assurance from OHRP) under certain circumstances. These include:

- o funding agency requirements
- o the UMBC investigator's role is limited to data analysis only
- o the research began at another institution prior to employment of the investigator at UMBC, and remains active only at the other institution (and any funds supporting the research remain under control of the non-UMBC institution);
- o and/or the research is not greater than minimal risk.

Investigators from institutions that *do not* have a Federalwide Assurance

Investigators, who are not faculty, staff, students, or employees of the University of Maryland, Baltimore County may be covered under the UMBC's Federalwide Assurance (FWA) only in accordance with the submission of a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. (source: [Guidance on Extension of an FWA to](#)

Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement)

The **Individual Investigator Agreement** is a commitment statement of an unaffiliated investigator to institutional human subject protection policies and IRB oversight. This agreement is submitted by the outside investigator to the UMBC IRB Chair (along with a copy of his/her Curriculum Vitae), and signed by the investigator. The IRB Chair will forward to the Institutional Official of UMBC for review and approval. The original Investigator Agreement will be retained by the UMBC IRB, with a copy sent to the requesting investigator. This agreement must be kept on file and made available to OHRP upon request. The investigator must also provide documentation that he/she has successfully completed an education/training program that provides core knowledge on the ethical principles and regulatory requirements that govern the use of human participants in research.

The investigator then submits the appropriate IRB application forms for review and approval by the UMBC IRB. Approval must be obtained before such research begins. Application guidelines and forms may be downloaded from the [IRB Forms page](#).

Any non-assured institution may choose to submit an assurance to OHRP for approval rather than agree to the use of the Individual Investigator Agreement that extends another institution's FWA to cover a collaborating institutional investigator employed by the non-assured institution.

The institution who submits a Federalwide Assurance (FWA) retains ultimate responsibility for the protection of human subjects in all research in which the institution engages, including (i) safeguarding the rights and welfare of human subjects within its local research context; (ii) educating the members of its research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human subjects; and (iii) implementing, within its local research context, appropriate oversight mechanisms to ensure compliance. Consult the OHRP website (<http://www.hhs.gov/ohrp/assurances/>) for more information.

FOREIGN RESEARCH

Research conducted by UMBC investigators at another institution in foreign countries falls under University guidelines. Although they cannot be imposed on other cultures, the standards for ethical conduct cannot be lowered. Human participants in foreign countries deserve the same level of protection as participants in the United States.

UMBC has the primary responsibility to ensure that the project complies with United States regulations. In cases of social and behavioral research projects, investigators may wish to follow this advice*:

The Common Rule § 101 (h) discusses foreign human subjects regulations and procedures for substituting them for US regulations. When an appropriate foreign IRB exists the regulations foresee involving it in reviewing the research. This regulation is most germane to biomedical research, as few foreign countries apply human subjects regulations to social and behavioral science. In many foreign countries IRBs deal only with biomedical research and will refuse to extend their purview to cover social and behavioral science. In other foreign situations there will be no analogue to an IRB and the concept may be irrelevant. When this situation occurs, the US institution remains the responsible authority and the services of a foreign IRB might not be necessary.

It may be necessary and appropriate for the IRB to enlist the services of a cultural expert knowledgeable about the customs and language in the society where the research will occur.

* *"Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research"*, National Science Foundation, <http://www.nsf.gov/bfa/dias/policy/hsfaq.htm>

ON-LINE OR INTERNET BASED RESEARCH

The incidence of on-line or Internet research has increased exponentially over the years, rapidly advancing ahead of efforts to create effective compliance guidelines. Internet communities (such as mailing lists, chat rooms, newsgroups, or discussion boards on websites) are rich sources of qualitative data for researchers. The IRB believes that online and Internet-based research protocols must address potential risks (e.g., violation of privacy, legal risks, and psychosocial stress) and provide the same level of protection as any other types of research involving human participants.

All studies, including those using computer and Internet technologies, must ensure that the procedures fulfill the principles of voluntary participation and informed consent, maintain the confidentiality of information obtained from or about human participants, and adequately address possible risks to participants including psychosocial stress and related risks. Participation by minors must be addressed in the protocol application.

The following guidelines are offered to help researchers plan, propose, and implement on-line or Internet research:

Recruitment:

Online and internet-based procedures for advertising and recruiting study participants (e.g., internet advertising, e-mail solicitation) must follow the IRB guidelines for recruitment that apply to any traditional media, such as newspapers and bulletin boards.

Data Collection:

It is strongly recommended that data collected from human participants over computer networks be transmitted in encrypted format. This helps insure that any data intercepted during transmission cannot be decoded and that individual responses cannot be traced back to an individual respondent. The highest level of data encryption should be employed, within the limits of availability and feasibility. Participants may be required to use a specific type or version of browser software.

Data Storage:

All personal identifying information should be kept separate from the data, and data should be stored in encrypted format. Researchers are advised to use pseudonyms when reporting results.

Observation of Internet activity:

This usually involves such activities as gathering information about the use of the Internet, recording user information or users' comments. Examples include: participant observation of an on-line discussion group, using "cookies" to track web sites visited, or asking visitors to a web site to provide demographic information. The human subjects issues involved in this type of research generally involve consent/disclosure issues. Investigators need to indicate to the IRB how they intend to obtain the subjects' consent to use this information for research. As with other types of participant observation, investigators generally must disclose their role as researchers to the group participants.

Informed Consent:

For anonymous web-based surveys, participants would still need to be presented with the consent information and level of potential risk as a result of participating in the research, but would be informed that their consent is implied by submitting the completed survey. Other web-based surveys must include "I agree" or "I do not agree" buttons on the website for participants to click their choice of whether or not they consent to participate. A cover letter/consent page should indicate that by clicking on a "I agree" link, subjects are consenting to participate. This page should also include an e-mail address in addition to a telephone number(s) to withdraw consent and remove data, to the extent possible, upon request of the respondent.

Click on the below to download:

[Sample web-based survey cover page](#)

E-mail solicitations requesting participation in a study should contain a version of the approved cover letter and consent forms. Participants must be informed that by replying to the e-mail and completing the requested task(s) constitutes consent.

With all of the above cases, researchers must request a Waiver of Written Informed Consent from the IRB, documenting how and why written consent would not be appropriate, and what format will be used to provide consent information to participants.

Confidentiality or Anonymity:

Researchers conducting web-based research should be careful not to make guarantees of confidentiality or anonymity, as the security of online transmissions is in question. Investigators need to address how they intend to assure confidentiality, keeping in mind that the degree of concern over confidentiality is directly related to the sensitivity of the data. Data transmitted via e-mail cannot be anonymous without the use of additional steps. Because respondents' electronic addresses are typically provided when they return such surveys by e-mail, PIs should devise a plan for stripping such information to maintain the confidentiality and anonymity of respondents' names.

The researcher should also state how the confidentiality of the data will be maintained, for instance, when a survey will be posted online through a third party like Survey Monkey or Zoomerang, so that email addresses or web URLs will not be noted by the researcher.

Data submitted over the web can only be anonymous if software is used to store the information directly in a database without identifiers; otherwise identifiers are attached to the data. Web servers automatically store a great deal of personal information about visitors to a web site and that information can be accessed by others.

Further reading:

Association for the Advancement of Science, [Ethical and Legal Aspects of Human Subjects Research on the Internet](#) (.pdf)

Association of Internet Researchers, [Ethical decision-making and Internet research](#)

American Psychological Association, [Psychological Research Online: Report of Board of Scientific Affairs' Advisory Group on the Conduct of Research on the Internet](#)

ORAL HISTORY RESEARCH

All oral history interviews must conform to national standards of practice, such as those found in the guidelines at the [Oral History Association](#) web site. According to the Office of Human Research Protections (OHRP), oral history interviewing activities, *in general*, are not designed to contribute to generalizable knowledge and do not meet the definition of research offered by the Department of Health and Human Services. The Oral History Association and the American Historical Association have issued guidelines for their members about oral history projects. The guidelines take into account many concerns that an IRB would want to consider. The OHRP has concurred the OHA and AHA that most oral history projects are not research as defined by the HHS regulations governing human subjects research. However, some oral history interviewing projects may meet the definition of research.

To assist individuals in determining when oral history activities require human subjects review, the IRB is providing the [following information from Michael Carome](#) (OHRP). This information represents a response to Northern Illinois University's request for clarification regarding oral history projects. In short, this guidance maintains that so long as oral history activities meet the federal definition of research according to 45 CFR 46.102(d), then they are still subject to IRB review. Therefore, investigators will be required to follow UMBC's procedure for exempt review.

Investigators wishing to conduct oral histories may want to contact Dr. [Joseph Tatarewicz](#), [Department of History](#) or Dr. [Barry Lanman](#), Director of the [Martha Ross Center for Oral History](#) to discuss strategies in developing projects, interview and surveys.

GRADUATE AND UNDERGRADUATE RESEARCH METHODOLOGY COURSE RESEARCH

The IRB recognizes that graduate and undergraduate research methodology courses are designed to teach students research skills through a combination of readings, lectures and research activities or projects. The purpose of such research projects is for the student to apply what is taught (i.e. use skills outside of the classroom) rather than to contribute to existing research literature in a field. Accordingly, the IRB has developed special guidelines for such class projects involving participants other than class members. Students must discuss class projects with their instructors prior to initiating the project.

An instructor who wishes to make use of this abbreviated review procedure, must first review each student's topic to determine its acceptability and then submit according to the procedures described below.

NOTE: Students contemplating using a class-based project as part of an undergraduate honor's thesis, master's thesis, doctoral dissertation, independent study project or submitting it for professional publication or presentation, must follow the traditional IRB review procedures before commencing the project.

Choosing an Acceptable Topic

Only non-sensitive information may be collected from participants. No personal identifiers (e.g., name, social security number) may be included on questionnaires. The following types of projects **CANNOT** be approved by instructors through this review procedure:

Any project involving participants under the age of 18

Any project involving deception of participants

Any project in which participants could reasonably feel physically or psychologically threatened by the investigator (including use of weapons, verbal threats, striking an intimidating pose)

Any project involving collection of information about participants' own:

- sexual history (including AIDS, rape, date-rape, abuse, use of contraception, pregnancy, abortions)
- religious orientation and views
- mental health history (including suicide ideation, depression, eating disorders, compulsive behaviors, treatment for psychiatric disorders)
- substance use and abuse (including alcohol and illegal drugs)
- war experiences
- criminal history
- racial, ethnic biases or views
- medical history

2) Although students **may not collect personal information** of a sensitive nature from participants, they may ask participants to make judgments about behaviors of anonymous others. For example, participants may be asked to read about a crime and be asked to judge the appropriateness of the sentence as a factor of characteristics of the perpetrator.

3) Regardless of the project, students **may not use language** that is inflammatory (including racial or sexual slurs and obscenities)

Course instructors must download and submit a Class Project Research Application **each semester**. This application will include a descriptive title of each student project, the student investigator's name, the type and estimated number of subjects that will be enrolled and a description of how confidentiality will be maintained.

Submission of this application will certify to the IRB:

- a) The instructor and all teaching assistants are fully aware of and agree to comply with the policies and procedures that regulate the UMBC human research subjects protection program.
- b) The instructor and all teaching assistants have completed the UMBC IRB Investigator Education Program and have submitted a signed completion form to the IRB. These can be submitted with the Class Project Research Application form.
- c) The instructor and teaching assistants have discussed the aspects of human research protection in the coursework and demonstrate this by submitting a syllabus indicating where such discussion occurs.
- d) The instructor and teaching assistants will provide supervision to students on all phases of their research projects to ensure that these are conducted in compliance with UMBC IRB policies and procedures.
- e) The students enrolled in these classes have familiarized themselves with the requirements associated with the use of human subjects in research, such as maintaining confidentiality and obtaining proper informed consent before a project begins. Thus, they too need to complete the IRB Investigator Educator Program.

Click on the below to download:

[Class Research Project Application](#)
[Instructions for developing a consent form for class projects](#)
[Class Research Project Report](#)

Instructors of these courses will be made **ex-officio members** of the IRB during the semesters when they are teaching research courses. Acting in this capacity, instructors will have the authority to approve proposed projects that fulfill one or another category associated with exempt research. Additionally, course instructors carry the responsibility that he or she are accountable for the design, conduct and oversight of all projects undertaken by students in these classes. Students wanting to collect data from human subjects as part of the requirements for a specific

class may conduct research (surveys, opinion gathering, etc) that is not specific to the behaviors and/or experiences of the interviewees, as long as consent is obtained and information is collected anonymously. A sample consent form may be found here to assist student in the development of an appropriate consent document.

End of Semester Report Procedures

Course instructors are required to download and file a Class Research Project Report by the end of the semester providing the following information:

- a) a listing of all course instructor approved projects, indicating the appropriate exempt review category, along with information on the students [name, title etc.] responsible for data collection associated with such projects. An abstract of each project must accompany this report.
- b) that details be provided about any problems occurring in connection with the administration of any of the exempt projects.
- c) an assurance is given that any and all signed consent forms collected as a part of these student projects are to be kept on file, in a secure location, until the end of the following semester, after which time, they are to be destroyed.

Submission of this report is due within two (2) weeks of the end of the semester.

Compliance with the Procedure

A failure to comply with any aspect of this procedure could result in the Instructor losing the privilege of serving as an ex-officio member of the IRB the next time he or she teaches any relevant research or methodology courses. If such occurs, projects from students will need to be submitted in the traditional manner.

PROTOCOL ADMINISTRATION

SUBMITTING A PROTOCOL

Principal investigators may make the initial determination about the type of review appropriate to the project. However, final determination on the type of review rests with the IRB. If another type of review is more appropriate, the project will be reviewed under that review procedure and the PI notified. Click on the below review categories for more information about the application and review process.

[Exempt](#)

[Expedited Review](#)

[Full Board Review](#)

CONSENT AND ASSENT GUIDELINES

According to Federal Regulations ([45 CFR 46.116](#)), no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The written presentation of information in the consent form is used to document the basis for consent and for the subject's future reference. Remember that obtaining participant consent is a process. The consent form is

merely the documentation of informed consent and **does not, in and of itself, constitute informed consent**. The fact that a subject signed a consent form does not mean that he/she understood what was being agreed to or truly gave their voluntary consent. Consent must be given without coercion or undue influence.

Confidentiality

Provisions for confidentiality must be specified as well as a description of procedures for protecting privacy, including specific information regarding how data will be stored to ensure security and confidentiality. If data are to be in the form of audio/video tape recordings or photographs, procedures protecting confidentiality should be described. Be sure to describe to participants the steps used to preserve confidentiality. In the course of certain projects, confidentiality may not be absolute or perfect. This must be expressed to participants. There are some circumstances where research staff might be required by law to share information provided by participants. For example, if an interviewer has reason to believe a child or elderly person is being neglected or abused (or has been abused), the interviewer is required by Maryland state law to file a report with the appropriate agencies. Similarly, if a participant reports he/she has been abused in the past, the interviewer may also have to file a report. An interviewer may also find it necessary to warn an intended victim, notify police or seek hospital based treatment for a participant, if a participant threatens serious harm to him/herself or another person. An explanation in the consent form, in this section, must be provided in clear, non-jargon language.

Maryland state abuse reporting guidelines may be found at:

Child Protective Services - <http://www.dhr.state.md.us/cps/report.htm>

Adult Protective Services - <http://www.dhr.state.md.us/how/seradult/protect.htm>

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Additional information and directives for Certificates of Confidentiality may be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm>

Anonymity

An anonymous study means there is NO WAY ANYONE can tell if a person was a participant in the study and they cannot be identified by the information they give, (including the investigator). Even if data is coded, it can be de-coded and become identifiable. A confidential study means that while their identity potentially could be determined from the information they give, steps will be taken to insure that they will not be identified. Be sure to describe to participants the steps used to preserve confidentiality. A study cannot be both confidential and anonymous. If confidentiality/anonymity cannot be ensured, clearly state this under the "risk" section of the consent form.

Consent Form Signatures

Federal regulations at [45 CFR 46.117](#) require written informed consent, one that is approved by the IRB and signed by the participant or the participant's legal representative and the principal investigator. The originally signed and dated consent document (with the IRB approval stamp) is valid for the approved time period the subject participates in the research. Participants do not need to re-sign a consent form throughout the term of the protocol approval period. Only subjects

who are new and added to the existing pool of participants must sign a consent form.

Revisions to previously approved consent forms may occur during a project period due to changes in procedures or identification of serious or adverse events. These revisions must be documented using the protocol modification process or at the time of continuing renewal. In any event, all participants who had previously signed a consent form must be provided this new information with the option of remaining in the study.

Click on the below to download:

[General instructions and helpful hints to create a consent form](#)

[A blank informed consent document](#)

[A sample parental permission \(consent\) form](#)

[An addendum to a currently approved consent form](#)

Consent Forms Approved at Other Institutions

Many human research protocols conducted at UMBC involve collaboration with researchers from other institutions. At times, UMBC faculty members, masters and/or dissertation students are listed as a co-investigator on a collaborative project, with that institution's IRB reviewing and approving the research protocol. External IRB institutional approval is accepted by the UMBC IRB; however, while the faculty member or student is listed on the consent documents as a co-investigator, no information is provided to potential participants of whom to contact at UMBC in the event of asking questions or addressing issues or problems. The purpose of this addition will provide complete and full information to participants about who is involved with the study and whom to contact with questions and concerns. Investigators are reminded to add a statement to the *Whom to Contact* section of the consent documents such as *"In addition, this study has been reviewed and approved by the UMBC Institutional Review Board (IRB). A representative of that Board, from the Human and Animal Research Protections Office, is available to discuss the review process or my rights as a research participant. Contact information of the Office is (410) 455-2737 or HARPO@umbc.edu."*

Documenting child assent

Children are considered a vulnerable research population because their intellectual and emotional capacities are limited and they are legally incompetent to give valid consent. Special procedures and considerations are, therefore, required by the Federal regulations for the review of research involving children. "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd>.

In most cases, these are individuals under the age of 21 years. However, in the state of Maryland, individuals are adults and of legal age (released from parental authority), when one attains the age of 18 years. Minors are those individuals who have not attained the age of eighteen years (source: http://mlis.state.md.us/cgi-win/web_statutes.exe - section § 24).

In almost all cases, written consent from a parent or legal guardian must be obtained if the research involves children under the age of 18. In cases where child abuse is an issue, the requirement for parental consent can be waived.

Documentation of assent is required for participants between the ages 7 and 18 years of age

unless the participant is incapable, either mentally or emotionally, of being reasonably consulted about participating. The assent form, submitted to the IRB for review, should include a simplified version of the elements of informed consent, such as an explanation, at a level appropriate to the child's age, maturity and condition, of the procedure(s) to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

The consent form (for parents/guardians) and assent form (for minors) must be prepared as two separate documents. (NOTE: Participants under the age of 18 will need to complete an Assent form; a separate parental consent form is required for these participants providing parental permission to participate)

Click on the below to download:

[General instructions and sample to create an assent form](#)

Waiver of Parental Permission

A waiver of the requirement for parental permission if the research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), provided that an appropriate mechanism for protecting the children who will participate as subjects is substituted, and that the waiver is not otherwise inconsistent with federal or state law ([45 C.F.R. 46.408\(c\)](#)). When requesting a waiver of written documentation of consent under 45 CFR 46.116, 45 CFR 46.117, or 45 CFR 46.408(c), a justification *must* be provided. **The type of research will need to be minimal risk or less.**

Click on the below to download:

[General instructions and sample to create a waiver of parental permission form](#)

WAIVER OF THE REQUIREMENT FOR WRITTEN CONSENT

Waiver of Written Consent

Informed consent is more of a process, rather than a means for obtaining a signature. Therefore, documentation of the consent process may not always be required. Instead, verbal consent might be more appropriate for certain populations (including non-literate or politically vulnerable populations) or certain types of anonymous, low-risk research. Verbal consent means that the potential research subject is read a verbal version (script) of the consent form.

Information sheets may also be used to describe the study and the elements of informed consent may be left with a participant following the informed consent process, but a participant is not required to sign. Investigators must understand that a justification for a waiver is not the risk to a participant in answering the phone, carrying on a conversation, or completing a written questionnaire, but in the content of the questions and possible answers. Only the IRB can make the determination to waive some (written) or all (written and verbal) consent requirements. Federal regulations at [45 CFR 46.117](#) require written informed consent (meaning the use of an IRB-approved written consent form which is signed by the participant or the participant's legal representative). Occasionally there are reasons to waive written consent or to alter the requirements of consent. Evidence that investigators have provided participants information must be maintained in the protocol file. It is recommended that investigators keep a log of those who were approached about the study and offered verbal consent. A simple chart, numbered sequentially without identifiers, is sufficient.

Investigators must submit a Waiver of Written Consent Request form with the protocol application

in order to be considered by the IRB. As described above, an **oral consent script** or a **telephone consent script** must be submitted to the IRB for review and approval. **Information sheets** must be placed on official university letterhead and contain all the same information as a consent form would, except that it is not signed by the subject. The information sheet must also be submitted to the IRB for review and approval. Samples of the script and the information sheet are found in the Waiver of Written Consent Request form.

Click on the below to download:

[General instructions to request a Waiver of Written Consent](#)

[A sample web-based survey cover page](#)

[A sample Oral Consent Script](#)

[A sample Information Sheet Consent](#)

To request a waiver of written informed consent, the investigator must specifically address this in the consent section of the IRB application and complete a Waiver of Signed Informed Consent form. The request must address the following criteria:

The principal risks are those associated with a breach of confidentiality regarding the subject's participation in the research, and the consent document is the only record linking the subject to the research; *and*

Study participation presents minimal risk of harm to the subject, and the activity normally does not require consent except for the fact that this is a research study.

Examples of studies where a waiver of written consent MAY be approved:

Interviews with potential groups of illegal immigrants about their experience in which these individuals will be interviewed in a safe space.

Conducting phone or web-based interviews with political staffers (who work in a very public position) about how recent fundraising rules have changed the campaign process.

A survey of women who have left abusive partners and the goal is to assess factors that affected their ability to leave.

[Research qualifying for exempt review does not need to obtain waivers of written consent from the IRB.](#)

Waiver to obtain informed consent or alter elements of informed consent

Federal regulations allow for the waiver of both written and verbal consent under certain circumstances. The IRB may approve a consent procedure which does not include some of prescribed elements of informed consent where the research or subject would be jeopardized by full consent procedure.

Examples of studies where a waiver of all consent elements MAY be approved:

A psychological study that is actually about peer pressure but participants are told the study is about perception of visual phenomenon. Deception is required to adequately measure peer pressure.

A study that requires covert observation of interpersonal behavior and, if participants know they are being observed, they may alter their behavior.

To request a waiver of to obtain or alter elements of informed consent, the investigator must specifically address this in the consent section of the IRB application and complete a Waiver of Signed Informed Consent form. The request must address the following criteria:

the research should pose no more than minimal risk to subjects

the waiver or alteration will not adversely affect subjects' rights and/or welfare

it is not practicable to carry out the research without the waiver or alteration

information will be provided to the participants after participation is completed. If a debriefing statement is used, submit a copy with the IRB application.

HIPAA

HIPAA stands for the **H**ealth **I**nsurance **P**ortability & **A**ccountability **A**ct of 1996 (Public Law 104-191), which amends the Internal Revenue Service Code of 1986. It is also known as the Kennedy-Kassebaum Act.

The Department of Health of Human Services issued the **Privacy Rule**, resulting from HIPAA regulations, and became effective April 14, 2001. Compliance is required of all covered entities for the Privacy Rule on April 14, 2003.

In essence, the Rule specifies the actions required to protect the security and privacy of personally identifiable health care information and establishes the conditions for its use and disclosure.

HIPAA also identifies for severe civil and criminal penalties for noncompliance, including: -- fines up to \$25K for multiple violations of the same standard in a calendar year -- fines up to \$250K and/or imprisonment up to 10 years for knowing misuse of individually identifiable health information.

How the Privacy Rule Works

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, **covered entities** are permitted to use and disclose protected health information for research provided an individual gives written authorization to use or disclosure PHI unless such authorization is waived or excepted by an IRBs or Privacy Board. The use of decedent's information is protected by the Rule but authorization is not required.

In other words, a covered entity will make good faith effort to tell individuals how PHI will be used & disclosed and will not share a patient's PHI without their express permission (authorization).

The Privacy Rule does not replace or modify the human research protection regulations found in 45 CFR 46. The Privacy Rule exceeds privacy provisions found in 45 CFR 46 as it extends to decedents, applies to all research, regardless of funding or activity and extends the definition of "identifiable information".

What is individually identifiable or "protected health" information (PHI)?

The Privacy Rule defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. The Privacy Rule protects the privacy of **individually identifiable health information**, while at the same time setting conditions for researchers to have access to medical information when necessary to conduct vital research.

Health information is “information that relates to the past, present, or future physical or mental health or condition of the individual, or that relates to the provision of health care in the past, present or future.” **Identifiable** means information “that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual”

Examples of **identifiable health or protected health information, as defined by the regulations**, include names, telephone numbers, fax numbers, electronic mail addresses, social security numbers, Internet protocol (IP) address numbers, finger and voice prints and full face photographic images and any comparable images.

Who must comply with HIPAA?

As required by Congress in HIPAA, the Privacy Rule covers:

- Health plans
- Health care clearinghouses
- Health care providers who conduct certain financial and administrative transactions electronically. These electronic transactions are those for which standards have been adopted by the HHS Secretary under HIPAA, such as electronic billing and fund transfers.

These entities are called "**covered entities**". Examples of **covered entities** are physician offices, health plans, employers, public health authorities, EMS agencies, life insurers, clearinghouses, billing agencies, information systems vendors, service organizations, and universities.

UMBC's activities include both HIPAA covered and non-covered functions; the University is considered a “hybrid” HIPAA entity. Currently, only the University Health Center is designated HIPAA covered entity. ***Researchers who are not employed or are involved with research falling under the jurisdiction of the University Health Center are not covered by HIPAA; therefore, HIPAA regulations do not apply.*** Confidentiality of data collected must be maintained common sense procedures must be followed.

What does this mean for UMBC researchers?

The HIPAA Privacy Rule only applies if investigators use, receive and/or disclose protected health information (PHI) from a covered entity in the course of doing research with human subjects or human subject data.

Remember, researchers who are not employed or are involved with research falling under the jurisdiction of the University Health Center are not covered by HIPAA; therefore, HIPAA regulations do not apply.

Does HIPAA apply to Social/Behavioral Research? ⁽⁵⁾

Below are examples of projects that do not involve the use and/or creation of PHI:

- Obtaining individually identifiable health information not created or maintained by a covered entity.
- Acquiring non-treatment related data obtained from subjects within a covered entity. **For example, a researcher obtains individually identifiable health information from a subject within a covered entity using interviews, surveys or questionnaires. This information does not become part of the individual's medical/treatment records. While the study collects health related information and it occurs within a covered entity, the data is not PHI as it does not result from treatment or come from medical charts.**
- Obtaining data from a source that is not a covered entity. **For example, a researcher collects individually identifiable health information from participants (using interviews, surveys or questionnaires) at a community setting. While the study collects health related information, the data is not PHI as it does not come from a covered entity.**
- Using individually identifiable health information that is stored school records or individually identifiable health information that is stored in employee records by a covered entity acting in the role as an employer.

Here are a few guidelines to follow to remain with the spirit of HIPAA (*courtesy of J. Kevin Eckert, UMBC Sociology/Anthropology*):

- 1) *Respect the confidentiality of all protected health information*
- 2) *Keep all electronic, paper and spoken project communications regarding exiting or potential study participants strictly confidential and shared among research team members on a "need to know" basis only.*
- 3) *Verbal communication between research team members must be conducted within the confines of a fully enclosed space, such as an office or conference room. Access to these areas must be closed when conversations are in progress to prevent inadvertent communication of protected health information.*
- 4) *Regarding information regarding research subjects that is created, communicated, stored or processed:*
 - a) *all electronically stored information must be password protected*
 - b) *individual passwords are not to be shared with other research team members or outsiders*
 - c) *all paper records and photographs must be stored in a locked file cabinet*
 - d) *all interview tapes are to be stored in a locked file except when used for transcript preparation. Once data has been retrieved, these tapes are to be erased and destroyed.*
 - e) *when in use, computer screens and paper documents must be oriented in a manner that precludes their being viewed by non-research team members.*
 - f) *faxing of information must be kept to an absolute minimum and all faxed information must be covered with a cover sheet describing that confidentiality be observed by the recipient.*
 - g) *all information is to be de-identified as expeditiously as possible.*

In any event, participants from whom the investigator is collecting this type of data, must be informed that such data will be kept confidential, no identifying information will be maintained by the researcher and that any data will be kept in a secure location. A statement to this effect must be included in the participant's consent form in the "Confidentiality Statement".

If HIPAA applies to my research, what is required?

A UMBC researcher who wishes to use individually identifiable health information from a UMBC covered activity must first obtain a waiver of authorization or an authorization to use

and/or disclose PHI. These documents must be submitted with the IRB application for review and approval.

Click on the below to download:

[IRB Waiver of Authorization Request Form](#)

[HIPAA Authorization Form](#)

Note that research with human subjects that fall under the HIPAA guidelines, may be exempt, provided the data is truly anonymous and that all data is truly de-identified. **The Privacy Rule states that identifiers must be removed before information is considered de-identified.** Data that is not truly de-identified may require expedited or full board review.

Researchers who have questions about how HIPAA applies to their research may contact the Human and Animal Research Protections Office at 5-2737 or HARPO@umbc.edu.

Research Use / Disclosure **Without Individual Authorization**

To use or disclose protected health information ***without authorization by the research participant***, a researcher must obtain documented Institutional Review Board (IRB) Approval. An alteration or **waiver** of research participants' authorization for use/disclosure of information about them for research purposes must be approved by the IRB. An example for this involves records research, when researchers are unable to use de-identified information, and the research could not practicably be conducted if research participants' authorization were required. **The waiver form must accompany the IRB application upon submission for review.**

A **waiver of authorization** provided the request satisfies these criteria:

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

- an adequate plan to protect the identifiers from improper use and disclosure;
 - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to

and use of the protected health information.

Note that health information that is effectively de-identified is not considered protected health information. While this might be helpful with some research, the Privacy Rule states that identifiers must be removed before information is considered de-identified. Examples include names, telephone numbers, fax numbers, electronic mail addresses, social security numbers, Internet protocol (IP) address numbers, finger and voice prints and full face photographic images and any comparable images.

Data that does not contain both health information **and** identifiers, such as de-identified data, which used and stored by a covered entity may be used without authorization or disclosure. The Privacy Rule states that in order for data to be truly de-identified, all of the above mentioned identifiers must be removed. The source providing de-identified data must verify this and provide a statement there is statistically less than a "very small" risk an individual's identity can be detected. **A certification of de-identification must accompany the IRB application upon submission for review.**

Research Use / Disclosure With Individual Authorization

The Privacy Rule permits covered entities to use or disclose protected health information for research purposes ***when a research participant authorizes the use or disclosure of information about him or herself***. In this case, documentation of IRB approval of a waiver of authorization is not required for the use or disclosure of protected health information.

To use or disclose protected health information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the requirements of 45 CFR 164.508. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes. Special provisions apply:

- Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the "end of the research study;" and
- An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study.

A copy of the authorization form must be kept in the protocol file and a copy provided to the participant.

Reference Sources

1) Office for Civil Rights - HIPAA Medical Privacy - National Standards to Protect the Privacy of Personal Health Information, OCR Guidance Explaining Significant Aspects of the Privacy Rule - December 4, 2002 <http://www.hhs.gov/ocr/hipaa/privacy.html>

2) "The Impact of the HIPAA Privacy Rule on Academic Research", a white paper issued by the [American Council on Education](http://www.acenet.edu/washington/policyanalysis/HIPAA.pdf), November 22, 2002
<http://www.acenet.edu/washington/policyanalysis/HIPAA.pdf>

3) "HIPAA Privacy Rule Primer for the College or University Administrator" a white paper issued by the [American Council on Education](http://www.acenet.edu/washington/policyanalysis/HIPAA.2.pdf), December 17, 2002
<http://www.acenet.edu/washington/policyanalysis/HIPAA.2.pdf>

4) Department of Health and Human Services (HHS) - HIPAA Privacy Rule and Research (<http://privacyruleandresearch.nih.gov>)

5) University of South Florida, HIPAA Compliance Program, [Does HIPAA Apply to Social/Behavioral Research?](http://www.research.usf.edu/cs/hipaa.htm) (<http://www.research.usf.edu/cs/hipaa.htm>)

ADVERTISEMENTS AND CONTACT LETTERS

An advertisement is used to meet the specific project need to recruit research participants. As advertising and recruiting is part of the research procedure, investigators should keep in mind that these procedures are subject to approval by the IRB and should not proceed until approval is granted. The IRB requires that a copy of the planned advertisement be submitted with all applications.

Advertising and recruiting procedures must protect potential participants' confidentiality. In particular, names and contact information for potential participants is to be collected and maintained in a confidential manner. Additionally, advertisements must clearly state that volunteers are being recruited for research purposes.

Advertisements must :

- not appear as coercive
- include name and phone number of the investigator
- describe the general purpose of the research and include a summary of the eligibility criteria that will be used to admit subjects into the study
- provide a straightforward and truthful description of the benefits
- indicate the location of the research and the person to contact for further information

Recruitment methods may include:

- Verbal recruitment (via telephone or in-person): investigators must provide the IRB with a script of the verbal recruitment process, detailing the intended "contents" of the delivery.
- Electronic recruitment (via e-mail, web sites, or listservs): investigators must provide the IRB with a version of the e-mail script or web site view detailing the recruitment process and how consent will be obtained. An investigator may be required to provide the IRB with access to the proposed web address.
- Recruitment by mail: Investigators must provide the IRB with the materials that would be used for the mailing campaign
- Recruitment by advertisements: Investigators must provide the IRB with the intended proposed advertisements, flyers, and ads to recruit participants for research purposes.

Furthermore, the IRB approval number must be stamped and printed on the advertisement or flyer and should include this statement in the body of the advertisement:

"This study has been approved by the UMBC Institutional Review Board for use of human participants but is not endorsed by the campus administration or representatives of the UMBC Institutional Review Board"

Any announcement, in whichever format (print or electronic) that does not contain this phrasing should not be run.

A contact letter to potential research participants should briefly describe:

- a. The study and the reason for the contact
- b. How the subject will be contacted

The contact letter should clearly state that participation is voluntary and the subject has the right to refuse to participate. Most importantly, the contact letter should not be coercive. The contact letter should clearly provide a way for the subject to refuse to participate (e.g., consent forms to return by mail if agreeing to participate). If the contact letter package also contains a consent form and questionnaire and participants who do not respond are to receive follow up calls, the letter should state this clearly.

PAYMENTS TO PARTICIPANTS

Research participants may be reimbursed for travel or be offered in-kind compensation (including course credit) for their participation in research. While these payments in money or in kind to research subjects are generally allowable with appropriate informed consent, incentives should not be so large to persuade participants to take undue risks or volunteer against their better judgment. Payments or rewards that undermine a person's capacity to exercise free choice invalidate consent.

Direct payments or other forms of remuneration offered as an incentive or reward for participation should not be considered a "benefit" to be gained from research.

Review of participant costs in the protocol application

The IRB will consider whether paid participants in research are recruited fairly, informed adequately, and paid appropriately. Additionally, the IRB must determine whether the rewards offered for participation in research constitute undue inducement, when a subjects' medical, employment, educational, financial, emotional status is considered. The IRB will attempt to make sure that prospective subjects realize that their participation is voluntary, and that choosing not to participate will not adversely affect their relationship with the institution or its staff in any way. To make this determination, IRBs should know who the subjects will be, what incentives are being offered, and the conditions under which the offer will be made. Therefore, the purpose of incentives as well as the schedules of payment must be clearly stated in the protocol application and referenced, as appropriate, in the informed consent document.

Additional information and guidance regarding payments to research participants may be found in Grady C, Dickert N, Jawetz T, Gensler G, Emanuel E., An analysis of U.S. practices of paying research participants. *Contemp Clin Trials* 2005 Jun;26(3):365-75. A [link to this article](#) is available from [PubMed Central](#) (National Library of Medicine)

Tracking of participant costs

UMBC investigators are required, when using funds obtained from the campus Working Fund, to account for monies disbursed during the course of a project. This is a necessary component of financial auditing. However, this accounting must be done in a way that participant confidentiality is not compromised. Using any type of identifier will void confidentiality protection mechanisms and possibly contradict what the participant was informed about in the consent document.

For this purpose, investigators should maintain a log of expenses, tracking each expense by subject ID, the amount paid and when payment occurred. This documentation is kept in the protocol file. UMBC Accounting has created a "Receipt for Funds Disbursed to a Study Participant" that will serve as an audit back-up support document. This form does not track individual participant identifiers, but will require the investigator certify payment was made and for what purpose.

Contact Linda Miller (x5-3288) in UMBC Accounting for more information.

ADVERSE EVENTS

Investigators are responsible for prompt reporting to the IRB of "any unanticipated problems involving risks to subjects or others..." ([45CFR46.103.b \(5\)](#)). The IRB maintains responsibility for initial assessment of the risk/ benefit ratio in a research activity involving human participants. During the course of the project, investigators are required to promptly inform the IRB of any unanticipated negative effect or undesirable experience that is **possibly, probably or definitely** related to study procedure(s).

If this relationship can be definitively ruled out, then the adverse event should not be reported to the IRB. If in doubt, it is best to err on the side of caution by contacting the Human and Animal Protections Research Office at (410) 455-2737 or HARPO@umbc.edu.

Adverse events are not necessarily physical in nature; attention must be paid to psychological harm (such as depression, thoughts of suicide, etc), threats to privacy or subject safety. An event is considered serious and must be reported when the participant experiences an unusually strong response, recurring problems, and/or death.

For the social and behavioral sciences, what does "serious," "unexpected," etc. mean?

The IRB is aware of the fact that it may be difficult for an investigator to determine what constitutes a "serious" or "unexpected" event. Therefore, as with determinations of whether or not a research project is exempt from federal regulations regarding human participants in research, investigators are discouraged from making the final determination as to whether or not an adverse reaction is serious enough or unexpected enough to warrant review by the IRB

All adverse reactions to study procedures and unexpected events, the degree or severity of which is not consistent with the risks described in the current Investigator's protocol and/or consent form, should be reported to the IRB for review

source of definition: FAQs re Adverse Event Reporting, Social and Behavioral Sciences Institutional Review Board, University at Buffalo, The State University of New York,
<http://cas.buffalo.edu/dean/hsrc/>

An investigator must use his/her expertise along with the known risks associated with study participation and will be asked to provide their opinion as to whether the proposed changes to the protocol or consent forms are required.

Click on the below to download:

[Adverse Event Report](#)

The IRB will determine if the study and/or consent form should be updated, and/or currently enrolled subjects should be informed of the new information to determine whether they wish to continue. If risks to subjects have changed such that the study must be stopped, all enrollment must cease and the research project placed on hold pending resolution by the IRB. Investigators will be notified of the appropriate changes to make for submission to the IRB for review and approval - usually submitted in the form of an amendment.

Reports of adverse events occurring on UMBC protocols should be submitted to the IRB Chair **within five (5) days of occurrence**, after first awareness of the problem. If the event is

considered serious or life threatening, proper notification will be made by the principal investigator, via the IRB chair, to the UMBC Institutional Official and to all applicable Federal agencies.

ANNUAL CONTINUATIONS AND RENEWALS

The IRB is responsible for the continuing review of research to ensure that the rights and welfare of human participants are being protected. Special attention will be paid to determine whether new information or unanticipated risks were discovered during the research.

All expedited and full board approved human subject protocols at UMBC are approved for a total of five years. A protocol is initially approved for a period of up to 12 months. Four (4) continuations or renewals may be requested, each for a period of up to 12 additional months. Continuing review of research previously approved by the IRB at a convened meeting may be performed by the IRB where, at the time of renewal, the research:

is permanently closed to the enrollment of new subjects, all subjects have completed all research related interventions, and the research remains active only for long-term follow-up of subjects;

had no subjects ever enrolled and no additional risks were identified;
where the remaining research activities are limited to data analysis.

OR

the research, where the IRB has determined and documented at a convened meeting, involves no greater than minimal risk and no additional risks have been identified.

Expedited Review Procedure - <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>).

The Human and Animal Protections Research Office will send the principal investigator an Annual Continuation Report Reminder in advance to the expiration of approval for a protocol approved via expedited review. The principal investigator, however, is responsible for timely submission of a continuation request. The request and all supportive materials must be submitted to the Human and Animal Protections Research Office at least four (4) weeks prior to the current protocol end date.

Click on the below to download:

[Annual Continuation Report](#)

NOTE: A protocol period lapses when no continuation request has been submitted prior to the expiration date. As such, no protocol activity may continue, including contact with participants and the use and analysis of collected data. If this occurs, the protocol will be administratively closed by the IRB; investigators listed on this protocol will not have new submissions reviewed until a closure report is received. The process for submitting a new protocol is required to resume project activities.

Prior to the end of the fifth year of the protocol, the Human and Animal Protections Research Office will send the investigator a notice of closure, stating the requirements for closing the protocol and submitting a new protocol for continuing the research project. Investigators, whose externally funded projects are not being renewed, may request a one-time, six month extension to complete data analysis and prepare a report for the funding agency. Requests must be made in writing to the IRB at least sixty (60) days prior to the termination of the project and submitted to the Human and Animal Protections Research Office.

Exempt Protocols

Under the Exempt category, the principal investigator is not required to submit a renewal request. If for any reason the status of the protocol changes and it is believed that the protocol is no longer exempt from IRB review and approval, please contact the Human and Animal Protections Research Office (HARPO@umbc.edu).

MODIFICATIONS TO PROTOCOLS

Any proposed change to an already approved human subject research protocol, measures, or informed consent document during the period of IRB approval must be submitted in writing to the IRB immediately for review and approval. An investigator cannot initiate the procedures/changes stated in the amendment **until IRB approval has been obtained**. An amendment to the protocol does not change the approval date. Investigators will be notified of approval of requests for minor changes in approximately one (1) week following submission.

Click on the below to download:

[Protocol Modification Request](#)

Determining whether a modification request should receive expedited or full convened committee review can be difficult. Most modifications will be handled through expedited review regardless of whether the original application was reviewed by the full board or expedited. However, modifications that substantially change the study design or that change the risk to subjects may require review by the full IRB. The IRB chair will make the decision about the type of review. The following definitions* may be helpful to investigators to determine the level of approval to pursue; investigators are encouraged to contact the Human and Animal Protections Research Office (HARPO@umbc.edu) with any questions prior to submitting the request.

Minor Changes

Definition: Minor changes have no substantive effect upon an approved protocol or reduce the protocol risk already approved by the IRB

Examples of minor changes are:

- 1) Changes in contact names, addresses, telephone numbers, advisor, ending date, adding a researcher, etc.
- 2) Scientific and/or therapeutic changes that leave the research population at the same or lower risk than risk(s) already approved
- 3) Changes in the consent form that reflect changes in scientific/therapeutic changes noted above
- 4) Adding additional subjects of the same type of population indicated in the original protocol
- 5) Changing the title of the protocol

Major Changes

Definition: Major changes are changes that may increase the research population's risk or are of questionable risk.

Examples of Major Changes are:

- 1) Adding a subject population different from those already approved
- 2) Adding questions to a questionnaire
- 3) Changing consent procedures which involves the reconsenting of subjects
- 4) Changing the location of the research from that which has already been approved for projects other than no risk survey/interview research.
- 5) Adding an element that may breach the confidentiality of the subject
- 6) Adding a deceptive element to the research or changing the debriefing procedures for already approved deception
- 7) Changing the way subjects are compensated for participation in research - such as increasing the amount, changing from a lottery to cash, etc.

*(definitions adapted from Kent State University - Human Subjects Review Board)

Note about changes to informed consent

Federal regulations (46.116 General requirements for informed consent) do not require reconsenting of subjects who have completed their active participation in the study, or of subjects who are still actively participating, when the proposed change will not affect their participation. However, when changes do occur in the conditions or the procedures of a study which alter how consent was previously obtained, the investigator should once again seek informed consent from the subjects. Those subjects who are presently enrolled and actively participating in the study should be informed of the change and reconsented if it might relate to the subjects' willingness to continue their participation in the study.

If reconsenting is necessary, investigators must submit a Request for Modification to a Protocol form as well as an Addendum to Informed Consent form.

Click on the below to download:

[Addendum to Informed Consent Form](#)

CLOSING A PROTOCOL

All expedited and full board approved human subject protocols at UMBC are approved for a total of five years. Prior to the end of the fifth year of the protocol, the Human and Animal Protections Research Office will send the investigator a notice of closure, stating the requirements for closing the protocol and submitting a new protocol for continuing the research project. Investigators, whose *externally funded projects are not being renewed*, may request a one-time, six month extension to complete data analysis and prepare a report for the funding agency. Requests must be made in writing to the IRB at least **sixty (60) days prior** to the termination of the project and submitted to the Human and Animal Protections Research Office.

As the activities of a research project come to an end, the principal investigator is responsible for submitting a closure report, indicating any research findings and/or outcome of the project. A closure report is also required if the investigator is leaving the university. The investigator must sign the closure report. In cases where the investigator is a student, the faculty advisor must cosign the report. Attach copies of any results, reports, articles (etc.) deemed necessary to support the closure of the protocol and forward to the Human and Animal Protections Research Office.

When is a protocol officially closed?

The procedure differs depending upon whether the study is minimal risk or higher. In cases where the project is **minimal risk or less**, protocol closure may occur when data collection is completed, when basic data analyses are completed and when all contact with participants has ended. The basic data analyses should allow the investigator to conclude with reasonable certainty that there are no further impacts from the study on the participants. If the investigator has stated in the protocols or informed participants that identifying information, which could be linked to participants, this deletion must be made prior to closing a protocol. *Note that a protocol closure does not affect an investigator's ability to write articles or publish. However, it does stop any ongoing or future contact between the investigator and participants.* All linkages to participants should be destroyed. Should the investigator decide future contact is needed with the participants, or to collect additional data, he/she must notify the IRB. Students completing research for their thesis or dissertation must, upon completion of the project activities (as defined above), submit a closure report.

Click on the below to download:

[Closure Report](#)

If a principal investigator does not respond to a continuation (renewal) request by the date the protocol is due to expire, the IRB, via the Human and Animal Protections Research Office, will administratively close the protocol. No protocol activity may continue, including contact with participants, the use of and/or the analysis of subject records and collected data.

PROTOCOL DEVIATIONS AND VIOLATIONS

As stated in the federal regulations ([45 CFR 46.113](#)), all protocol deviations and/or instances of noncompliance with IRB regulations must be reported to the IRB by the principal investigator as soon as the violations are discovered. The IRB has the authority to suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. The IRB also has "sanction," "suspend," or "terminate" approval if there has been serious or continuing non-compliance with the policies, requirements or determinations of the IRB.

Investigators not in compliance with IRB procedures will not be able to process new protocols or renew current projects until all concerns have been addressed and the investigator sends a letter to the IRB Chair acknowledging the error that was made.

Minor Protocol Deviations

As stated in the *Researcher's Guide*, investigators are responsible for conducting human with participants in compliance with federal regulations and UMBC's policies and procedures. Failure to comply with these administrative regulations may result in an individual investigator's ability to conduct research but can also affect the ability of all others at UMBC to perform human participant research. Non-compliance with regulations may be seen as protocol deviations. Deviations generally do not have substantive effects on the safety or well-being of research participants; do not affect the value of the data collected (meaning the violation does not confound the scientific analysis of the results); do not result from willful or knowing misconduct on the part of the investigator(s); and do not violate any ethical principles.

Common deviations in investigator compliance include:

- unreported changes in the IRB approved protocol or consent documents
- misuse or non-use of the IRB approved informed consent documents
- lapse in obtaining approval for continuing review
- failure to obtain IRB approval prior to starting research activities
- failure to file protocol modifications.

Problems such as these are often caused by an investigator failing to communicate effectively with the IRB. When such instances are discovered, the IRB will act promptly to halt the research,

ensure remedial action regarding compliance with federal and institutional human participant protection requirements.

Deviation Reporting Procedure

Investigators can almost always avoid protocol deviations by being aware of the IRB requirements and following the approved protocol. If a protocol deviation does occur, an investigator must ***immediately*** submit a protocol deviation reporting form to the IRB for review immediately upon discovery. This form will serve as the documentation for modifying the particular protocol; investigators must await IRB approval before implementing anticipated changes or modifications.

Click on the below to download:

[Protocol deviation reporting form](#)

Following the review of the reporting form, the IRB chair will notify the investigator in writing of the need to meet discuss the deviation and develop a plan to avoid such actions in the future. The results of the meeting will determine what must be done (if anything) to correct the conditions that lead to the deviation and what (if anything) must be communicated to the research participants. Participant enrollment may be suspended pending resolution of the problem or concern. The IRB chair will present a summary of the deviation, process, facts, and conclusions at the next scheduled convened IRB meeting.

Protocol Violations

Protocol violations emerge when there is a variance in a research study between the protocol that has been reviewed and approved by the IRB and the actual activities being performed. Reports may come from a variety of sources: participants, community members, research staff, etc. Reporting of violations will be made, in writing, to the IRB Chair; all reports will be held in the strictest of confidence and discussed within the confines of the fact-finding committee.

Protocol violations are those that:

- are un-approved by the IRB that caused substantive harm to research participants
- cause damage to the scientific integrity of the data collected
- result from evidence of willful or knowing misconduct on the part of the investigator
- impact on ethical principles

Violation Investigation Procedure

Incidents of alleged or known protocol violations may be investigated by the IRB via the following steps:

The IRB chair will create a fact finding committee, composed of

1. the IRB Chair
2. the Human and Animal Protections Research Office Administrator

3. the Associate Vice President for Research
4. two or more representatives from the PI's department or discipline, and
5. a representative from the UMBC Legal Counsel.

This committee will analyze all information gathered regarding the protocol violation and compare it to the approved protocol. When necessary, the committee will consult with experts in the specific discipline of research in order to make definitive, unbiased and educated decisions regarding the violation. A conclusion will then be made regarding the seriousness of the violation.

If the hearing committee finds any of the protocol violations criteria noted above, the IRB Chair will immediately suspend the protocol. (Note: this does not preclude the IRB chair from suspending the protocol in advance of the hearing if, in the chair's assessment, the conditions in 45 CFR 46.113 have been met and warrant an emergency protocol suspension). If suspension of the protocol results from harm to the enrolled research participants, the IRB chair will request that the PI's department chair assign PI duties to another qualified person. (Note: This change of PI also requires approval of the grant sponsor). In this situation the official action will be the suspension of the investigator (45 CFR 46.109 (d)).

Depending on the nature or the seriousness of the violation, the committee may elect to direct the IRB to audit all protocols that involve the investigator in question. If the findings of the hearing committee support research misconduct, the Vice President for Research will be notified. A summary of the violation, process, facts, and conclusions will be presented at the next scheduled IRB meeting. The IRB chair will notify the investigator in writing with copies to the PI's department chair, the appropriate dean, the Vice President for Research, and the Office for Human Research Protections. If an investigator disagrees with the findings or requirements of the Committee, investigators have the right to appeal the committee's decision to the Vice President for Research.

POST APPROVAL PROTOCOL MONITORING

The University of Maryland Baltimore County is required by federal regulation to exercise "appropriate oversight mechanisms" to insure that the institution's policies and procedures designed for protecting the rights and welfare of human subjects are being effectively applied in compliance with the Office for Human Research Protections (OHRP) approved Federalwide Assurance (FWA).

In essence, the University is required to perform post approval protocol monitoring (**PAPM**) to ensure that protocol activity remains within compliance with the approved FWA. Aside from compliance, the PAPM procedure will act as a vehicle for further educating researchers about human subject protection issues and improve the quality of research by detecting errors and/or omissions that might occur when performing research activities. A report of the PAPM review will be provided to the members of the Institutional Review Board.

The Human and Animal Protections Research Office make arrangements to meet personally with the investigator and/or research staff to examine the investigator's protocol file. Investigators should plan to allow for least one (1) hour for the Human and Animal Protections Research Office to conduct the review; while the investigator's presence is not required, it will be helpful to be present to answer any questions. Student investigators and faculty advisors should meet prior to the review to make arrangements for a meeting time and access to the protocol files.

The Human and Animal Protections Research Office will examine the following items in the protocol file:

The use of the IRB approved consent form (complete with the date stamp of approval). A comparison will be made of the number of subjects recruited vs. the number of consent forms on file. Projects with **approved waivers of written informed consent** must present evidence in the protocol file indicating how participants were informed about the purpose of the research project and the procedures conducted. **Secondary data analysis projects** will be evaluated on the adequacy of confidentiality protection.

The IRB approved measures and instruments

Copies of protocol correspondence between the investigator and the IRB, including a copy of the investigator(s) IRB Training Certificate.

Copies of continuation/renewal requests or progress reports

Reports of all adverse incidents and any follow-up to adverse incidents

The investigator's data storage medium will be examined to determine if the appropriate measures are undertaken to ensure confidentiality and minimize risk to participants. Applicable items to be reviewed include the use of a secured location (lock and key system), an updated firewall or virus protection program and secure data tracking systems.

Maintaining confidentiality of data sources is important while the study is active. Data should be stored in a secured location and identified by code numbers only. A master list must be kept in a separate location from the data, with only the investigator and his/her designee responsible for access to the data

If audio- and video-tapes have been used in the study, the recommended length of time to keeping tapes is three years beyond the completion of the study. However, data from audio- or video-tapes should be transcribed as soon as possible; once accomplished, these tapes should be erased or destroyed.

The results of the review must be kept in the investigator's protocol file. In addition, retention of signed consent forms and other relevant documents or the location of where these are maintained for at least five years past completion of the research activity for adult subjects and, for minor subjects, at least three years after reaching the age of 18, whichever is longer.

APPEALS OF IRB DECISIONS

Appeals regarding IRB decisions can be submitted, in writing, to the IRB by a principal investigator. Appeals are processed by an internal re-review mechanism or Ad Hoc Committee and outcomes are reported by the Human and Animal Protections Research Office to the person appealing. If the person appealing is not satisfied with this outcome, he/she can submit further appeal to the Institutional Official (the Vice President for Research). The Institutional Official may not approve any research that has not been approved by the IRB.

Research covered by these guidelines that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the UMBC. However, these officials may not approve the research if it has not been approved by the IRB.