Institutional Review Board Researcher's Guide

(apropos to the OHRP approved Federalwide Assurance, #00000069, which expires on 09/13/2016)

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.

ADVICE TO INVESTIGATORS

An investigator, as a **faculty (part-time or adjunct), staff, graduate students or undergraduate students,** 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

What is "research"?

"Research" is defined in the Code of Federal Regulations as "a systematic investigation that contributes to generalizable knowledge".

In other words, for the most part, an investigator will:

- be "engaged in research"
- propose an intention to explore a particular topic
- interact with a living person and
- have a plan to "generalize " the information by either publishing (e.g., in a journal) or presenting at a conference

If you have any doubt as to whether an activity constitutes research, please consult with the Office for Research Protections and Compliance 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:

- individuals who are asked to complete questionnaires, participate in interviews, or whose behavior is observed in daily activities
- 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
- oral history interviewees whose subjective perceptions are studied
- 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 who are faculty (part-time or adjunct), staff, graduate students or undergraduate students affiliated with UMBC and who are engaged in research, comply with both UMBC procedures and federal regulations regarding the protection of human subjects in protocol activities. 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

According to HHS regulations (45 CFR 46.115 (b)), investigators must retain the records in some form. HHS also says investigators should follow the institution's policies and procedures for retaining records.

The IRB's guidance for principal investigators is as follows:

The investigator must maintain this protocol file for at least five (5) years following protocol closure. Protocol files and records may be kept in hardcopy, electronic or other media format and must be accessible for inspection by authorized representatives of the UMBC IRB or HHS at reasonable times and in a reasonable manner. All files must be kept in a secure location.

All investigators must maintain a protocol file, which must include:

a. All correspondence between the investigator and the IRB (approvals, modifications, continuing review, etc.)
b. Copies of the IRB "stamp" approved signed and dated consent forms obtained from all participants, unless the IRB waived the requirement for informed consent or the documentation of informed consent. The IRB "stamp" will show date the IRB approved the use of the consent form and the end date for such use
c. Any data derived from the study, including completed survey instruments, measures, audio-visual recordings and transcripts.
d. IRB approved continuation reports

e. Reports of all protocol deviations, adverse incidents and unanticipated problems and any follow-up these incidents

If a student in 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.

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., the departing investigator, faculty advisor, and department chair). This notification must include the current contact information of the investigator (address and telephone number) should the investigator no longer be associated with UMBC.

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 is found at:
http://www.umbc.edu/research/ORPC/IRBmember.html

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.

IRB Subcommittees

The IRB has one designated subcommittee: the ABA Subcommittee of the IRB. Subcommittee membership comes from full-board members of the IRB who are selected by the IRB Chair. The

subcommittee performs the review of review research projects for students enrolled in the Applied Behavior Analysis (ABA) master's program. Members of the subcommittee will perform review, via the expedited review procedure, for research that fall within the definition of "minimal risk". The outcome of these reviews will be reported to the full committee. Research designated as "greater than minimal risk" will require review by the board at a convened meeting. The subcommittee may not vote on actions that normally require full board review. The subcommittee will pre-review these projects to obtain the necessary information for presentation at a convened meeting. In either case, the subcommittee will have access to subject matter experts to assist with the review.

Support

The IRB is supported by the UMBC Vice President for Research.

IRB MEETINGS

The UMBC Institutional Review Board meets during the academic year to review human subjects protocols. Reviews of full committee protocol submissions are performed at each of the scheduled meetings; exempt and expedited review applications may be submitted at any time.

The current meeting schedule is found at
http://www.umbc.edu/research/ORPC/IRBprotdevelop.html

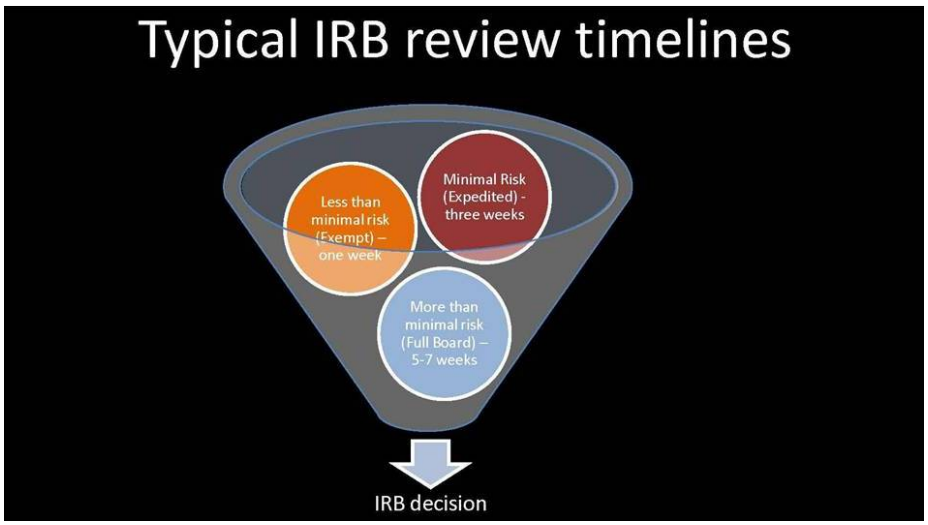
The review of all human use research takes place at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those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

See http://www.umbc.edu/research/ORPC/IRBprotdevelop.html for descriptions of the IRB's review processes.

Contact the Office for Research Protections and Compliance at 5-2737 or compliance@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 (i.e. quality improvement/quality assurance) 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 will arise 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 theQI/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. Searches of existing literature

6. 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.

7. Class Projects. The IRB recognizes that graduate and undergraduate research methodology courses are designed by instructors to teach students research skills through a combination of readings, lectures and research activities or projects. Such research projects allow the student to apply what is taught in the classroom rather than to contribute to existing research literature in a field. Other activities do present the opportunity to apply skills learned in the class setting with the public in general. It is these activities that may place the proposed activity under the regulatory definition of "research" (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102).

Instructors do have the responsibility of ensuring that the student is educated on the general principles of research ethics, human subject protection, and that the students receive human subjects training. Please use the below definitions to determine if a project requires IRB review.

Participants enrolled in a class setting

In general, classroom educational activities that instruct students in research methodologies and techniques usually do not fall within the federal definition of research as described in 45 CFR 46.102(d). As such, activities that involve data gathered (surveys/ questionnaires/ interviews/ observations of public behavior) solely as part of a classroom project that will not go outside the classroom setting will not require review by the IRB. Presentations of class research results at the end of a semester are acceptable.

Participants not enrolled in a class setting

Classroom projects (i.e. research methodology courses) are designed to teach students research. As above, such activities involve gathering data via surveys, questionnaires, interviews and/or observations of public behavior. The design of these projects will involve some type of interaction with individuals outside of the classroom setting. The IRB has developed special guidelines (http://www.umbc.edu/research/ORPC/IRB_researchmethods.html) to advise course instructors on what are acceptable topics, the use of the consent process and their responsibilities for student IRB education training and application forms. Students may use data collected in these projects to support their own independent projects (URCAD, masters, and dissertation). They must, however, submit a separate application (http://www.umbc.edu/research/ORPC/IRBprotdevelop.html) to the IRB for review.

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.html#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/asp/statutes_respond.asp?article=g1&section=24&Extension=HTML).

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 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 is 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 or 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 Office for Research Protections and Compliance 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,

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 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

In many areas of the social sciences, one of the most commonly used methods of research is the secondary analysis of publicly available files of data. The federal government as well as large data consolidation bureaus and consortiums provide public access to many data sets. Additionally, many federal funding programs as well as social science professional organizations and journals now require that researchers make the data they collect publicly available to encourage scholarly replication of research. Data may also available from previously IRB approved protocols where the data sets do not contain information that could be used to identify individual research participants.

Publicly available, de-identified sources

Under the federal regulations for human subjects (45 CFR Part 46), research involving publicly available data sets are exempt from IRB review:

- as long as the data come from sources that are publicly available
- and the data is deidentified and uncoded and stripped of identifiers.

Investigators who plan to use these *publicly available, de-identified sources* do not require prior IRB review - *no application is required*.

The IRB has created a list of pre-approved data holders whose archives include publicly available, de-identified data. Review this list and follow the respective links below to learn more about the access and download procedures each data source.

Caution: If you are designing a research project that merges more than one public data set and you recognize that this may increase the risk of identification of individual research participants, please contact the Office for Research Protections and Compliance.

To obtain pre-approval of other eligible data sets and archives, investigators must submit the following information to the IRB:

- The name of data set or data archive; and
- The URL for the data set/archive or other specific information on how to obtain the data set; and
- An abstract that describes the content and potential uses of the data set/archive.

If the IRB endorses the submission, the data set will be added to the list.

Publicly available but restricted sources

Data holders whose archives are available on a restricted basis will require the submission of an application for Expedited or full board review. Examples of such data involve:

- 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.

Investigators may wish to use the below list as a reference for sources of data sets available on a restricted basis:

- Inter-University Consortium for Political and Social Research
  - Public and Restricted
- National Center for Health Statistics
  - Data files through the NCHS Research Data Center (RDC)
- University of North Carolina at Chapel Hill, Carolina Population Center
  - The National Longitudinal Study of Adolescent Health - restricted
- U.S. Department of Education
  - National Center for Education Statistics *(search for restricted use data)*

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/hsfaqs.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.

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 should conform to the principles and standards of the practice, such as those proposed by the Oral History Association. These interviews may, in their design and/or implementation, contribute to generalizable knowledge which would constitute "research" as defined by DHHS regulations at 45 CFR part 46.

These general principles do apply to how UMBC researchers conduct oral history research. Specifically, two of these principles* reflect the IRB's ethical review mission to confirm that participants are allowed to review the material prior to public archive and decide if they do not wish any or all of the oral history archived as well as ensuring researchers make provisions for obtaining informed consent from all participants and document the process. These are:

- **Oral historians inform narrators about the nature and purpose of oral history interviewing in general and of their interview specifically**.

Oral historians insure that narrators voluntarily give their consent to be interviewed and understand that they can withdraw from the interview or refuse to answer a question at any time. Narrators may give this consent by signing a consent form or by recording an oral statement of consent prior to the interview.

UMBC uses an Oral History consent form to document the conversation. A template of this form is found here.

- **Interviewees hold the copyright to their interviews until and unless they transfer those rights to an individual or institution.**

This is done by the interviewee signing a release form or in exceptional circumstances recording an oral statement to the same effect.**UMBC uses a Deed of Gift which grants to the interviewer authorization to make any use of the content of recordings and the permission to deposit the recordings into one or more publicly accessible archives. The interviewee has the right to restrict access to all or portions of this interview or to place other access restrictions. The interviewee also has the option to remain anonymous in any interview transcript.** The Deed of Gift may be obtained from the Martha Ross Center for Oral History.

* Extracted from: http://www.oralhistory.org/do-oral-history/principles-and-practices/#general

At present, to meet its oversight responsibility, the UMBC IRB does require oral history researchers to submit an Exempt Application for review prior to initiating the study. Projects that may not fall within this classification may review expedited or full board review. Please contact the ORPC at compliance@umbc.edu with any questions.

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.

STUDENTS AS RESEARCHERS IN CLASS PROJECTS

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: Student investigators performing independent research or conducting senior theses, master's projects and doctoral dissertation research - please review the application and review information found here.

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

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

Course instructor responsibilities

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. Instructors of these courses will be considered 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.

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.

Use of the consent process

As student projects will not be individually reviewed by the IRB, the instructor is responsible for ensuring that student properly inform potential participants about the purpose of the study, how the data will be used, and stating that the data are anonymous, etc. Class research projects are granted an exemption from IRB review; student investigators, like all UMBC researchers, are ethically bound to follow the principles listed in the Belmont Report, particularly the first principle, respect for persons, which emphasizes the importance of ensuring that subjects are fully informed about the nature of a research project in order to make an informed decision to participate. The use of a signed consent document, for example in cases of anonymous data collection, would not be required, but those participants *must be informed* about the purpose of

the study. A student investigator will use an oral consent script explaining the purpose of the study, how the data will used, how the data will be kept anonymous, etc.

End of Semester Report Procedures

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.

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 of 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://dhr.maryland.gov/cps/

Adult Protective Services - http://dhr.maryland.gov/oas/protect.php

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.

Using the consent process in exempt review

Although a study is granted an exemption from IRB review, investigators are ethically bound to follow the principles listed in the Belmont Report, particularly the first principle, respect for persons, which emphasizes the importance of ensuring that subjects are fully informed about the nature of a research project in order to make an informed decision to participate. The use of a signed consent document, for example in cases of anonymous data collection, would not be required, but those participants must be informed about the purpose of the study. An investigator will provide a participant an IRB approved information sheet or use an oral consent script explaining the purpose of the study, how the data will used, how the data will be kept anonymous, etc.

At a minimum, the consent process of exempt studies must provide participants the following:

- Whom to contact about the study
- Brief description about the nature of the study.
- Time required for participation.
- Nature of data recorded (statement that data are recorded anonymously and/or no personal identifying information would be collected).
- Statement that participant can skip any questions.
- Statement that participation is voluntary
- Contact information for the IRB.

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 Office for Research Protections and Compliance, is available to discuss the review process or my rights as a research participant. Contact information of the Office is (410) 455-2737 or compliance@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).

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.***

WAIVING OR MODIFYING THE REQUIREMENT FOR 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 or Modification of Consent 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 Wavier of Written Consent Request form.

To request a waiver of modification to written informed consent, the investigator must specifically address this in the consent section of the IRB application and complete a Waiver or Modification of 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.

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 or Modification of 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.

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.

Note that research qualifying for exempt review does not need to obtain waivers of written consent from the IRB.

Waiver to obtain informed consent or modify 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.

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 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.

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 Office for Research Protections and Compliance at 5-2737 or compliance@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, 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, 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)

ADVERTISEMENTS AND RECRUITMENT MATERIALS

Advertisements and recruitment material are considered the first step of the informed consent process and are used to meet a project's recruit need for research participants. The IRB must approve all advertisement materials and recruitment methods and material during the initial protocol submission as well as for review and re-approval at the time of continuing review.

Advertising and recruiting procedures must protect potential participants' confidentiality. The content of recruitment materials and the method for communicating it cannot create undue influence or contain misleading or exculpatory language. Additionally, advertisements must clearly state that volunteers are being recruited for research purposes.

Advertisements

Examples of direct advertisement include posted notices, paid and unpaid newspaper solicitations or magazine advertisements (which may include public service announcements), websites, bulletin board announcements, recruitment posters, flyers Internet/website postings and solicitations by electronic mail.

Advertisements should contain information that provides enough detail to allow the prospective participant to determine his/her eligibility and interest. 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 not state or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form
- indicate the location of the research and the person to contact for further information

Advertisements must display the UMBC IRB approval stamp or at a minimum have the essentials of the validation stamp: "UMBC IRB, Approval On (date), Approved until (date)."

Recruitment

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.

Requesting approval of advertisements

1. Follow the submission instructions for an initial application or continuation review.
2. Identify and describe the method(s) of advertisement for research participants in the protocol document.
3. Attach a copy of the text or a printed copy of any website, newspaper, or other media advertisements for use initial application or continuation review submission for IRB review and approval.

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 participants' 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 a process to obtain funds from Working Fund and 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 Fleet (x5-2287 or lfleet@umbc.edu) in UMBC Accounting, Business Services 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 Office for Research Protections and Compliance at (410) 455-2737 or compliance@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.

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 Office for Research Protections and Compliance 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 Office for Research Protections and Compliance at least four (4) weeks prior to the current protocol end date.

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 Office for Research Protections and Compliance will send the investigator a notice of closure. If the protocol is to continue past the expiration date of the fifth year, and will involve continued interaction with and/or obtaining data from participants, a new protocol application is required for submission for review and approval. Investigators are reminded to begin this process early to avoid disruption of any ongoing and planned protocol activities. 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.

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 Office for Research Protections and Compliance (compliance@umbc.edu).

MODIFICATIONS TO PROTOCOLS

Most modifications may be approved administratively or may be handled through the expedited review process. Please review the below definitions to determine what type of change you wish to pursue. 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 using the below form 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 are encouraged to contact the ORPC (compliance@umbc.edu.) with any questions. Investigators will be notified of approval of requests for changes in approximately one (1) week following submission.

Examples of minor changes

a. Administrative changes
b. Minor consent form changes
c. Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods
d. Minor changes to study documents such as surveys, questionnaires or brochures
e. New study documents to be distributed to or seen by subjects that are similar in substance to

those previously approved
f. Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study
g. Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study
h. Editorial changes that clarify but do not alter the existing meaning of a document
i. Addition of or changes in study personnel
j. Addition of a new study site
k. Translations of materials already reviewed and approved by an IRB

Examples of major changes

a. Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects
b. Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study
c. Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm
d. New risk information that is substantial or adversely affects the risk/benefit ratio of the study
e. Significant changes to the study documents to be distributed to or seen by subjects
f. New study documents to be distributed to or seen by subjects that include information or questions that are substantively different from materials already approved by the IRB

Please highlight any proposed wording changes in the application form, consent documents, recruitment fliers, etc. by **highlighting in yellow and underlining** and attach those changed documents to this form. This will assist the reviewer with understanding the changes investigators are planning to make. **Please review these instructions when submitting a modification of protocol documents to the IRB**.

If reconsenting in necessary, investigators must submit a Request for Modification to a Protocol form as well as an 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 Office for Research Protections and Compliance 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 Office for Research Protections and Compliance.

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 Office for Research Protections and Compliance.

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 collect additional data, he/she must notify the IRB. The use of previously collected data from previously approved from an officially closed protocol may require the submission of an exemption application. Please consult the Office for Research Protections and Compliance with any questions.

If a principal investigators does not respond to a continuation (renewal) request by the date the protocol is due to expire, the IRB, via the Office for Research Protections and Compliance, 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.

Reopening a closed protocol

On occasion a principal investigator may make a request to the IRB to reopen a research study that was **administratively closed** (due to failure of the investigator to provide a proper continuing review form) or was **appropriately closed (**study was properly closed with submission of a closure report) in order to continue with the research.

To reopen the study, investigators should submit a brief cover letter to the IRB Chair, referencing the approval number and protocol title, requesting that the study be re-opened. The following information must be provided:

- an assurance that no participants have been enrolled during the time the study was not approved, that data collection during this unapproved time was discontinued and this is a continuation of the same study
- details of all pertinent information as to why this needs to be re-opened
- any amendments or changes in the study protocol, personnel, or consent documents (using the previously approved format)
- any documents relating to unanticipated events (i.e. Adverse Events)
- if participants need to be notified, indicate how this will be accomplished and by whom. Provide any documents—letters, email notifications, etc.

Requests to reopen a study must be made within 30 days of the notice of administrative closure or submission of the protocol closure report.

Note:

Investigators may conduct data queries after closure without reopening the study. Such queries occur without IRB approval if both of the following apply:

1. The data being queried is limited to that originally collected for the study as specified in the consent and authorization forms signed by subjects and/or the study protocol. No new data may be collected after study closure without prior IRB approval

AND

2. The data being queried is limited to the original timeframe during which data was collected for the study. No data outside the original timeframe for data collection can be queried after study closure without prior IRB approval.

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.

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 Office for Research Protections and Compliance 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 Office for Research Protections and Compliance 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 Office for Research Protections and Compliance 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 Office for Research Protections and Compliance 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 Office for Research Protections and Compliance 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.