

The University of Memphis Institutional Review Board

Procedures

Human Subjects Protections in Research

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Institutional Policy that Establishes the Institutional Review Board

**UM1742 - Issued: May 24, 2012**

At the University of Memphis, all human subjects' research activities come under the purview and oversight of the Research Support Services Office and the Institutional Review Board (IRB), irrespective of whether the research is funded or non-funded, minimal risk or more. The Human Subjects Protection policy applies to all University of Memphis faculty, staff, and students conducting human subjects' research on or off-campus (domestic or international sites) as well as visitors conducting research at the University of Memphis.

Researchers, including the faculty advisors of student researchers, must successfully complete online human subjects' protection training before submission to the IRB.

Human subjects protection is a collaborative effort by the researcher and the University of Memphis. The IRB is charged with the responsibility of protecting the rights and welfare of human subjects involved in research. The composition of the IRB and the number of members on the committee are in accordance with federal regulations. IRB members are appointed by the Vice-Provost for Research on the recommendation of the chairperson of the IRB. Members are appointed for renewable, three-year terms and include faculty and community members with expertise in the various disciplines engaged in human subjects' research on campus.

In accordance with 45 CFR 46, the IRB is required to report all instances of

non-compliance to the federal Office for Human Research Protections, Washington, DC. Additionally, non-compliance with this policy by faculty and staff members may result in one or more of the following:

- Censure;
- Removal from graduate faculty status;
- Suspension of research privileges at the University;
- Termination of employment

Non-compliance with this policy by students may jeopardize awarding of the degree being sought.

**Purpose**

This policy for the protection of human subjects is guided by ethical principles, federal law, and institutional standards. The guiding ethical principles are embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Compliance with this policy provides protections for human subjects as mandated by applicable laws, regulations, and standards of local, state and federal government agencies concerning the protection of human subjects, including the U.S. Code of Federal Regulations (CFR):

- Title 45 CFR 46, Protection of Human Subjects, U.S. Department of Health and Human Services (DHSS), Office for Human Research Protections (OHRP) and
- Title 21 CFR 50, 56, 312, 600 and 812 of the Food and Drug Administration (FDA)

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## Definitions

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- Human Subject** A living individual 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. (Title 45 CFR 46.102(f)).
- Research** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Title 45 CFR 46.102(d)).
- Minimal Review** Research activities involving human subjects that are **exempt** from IRB review are identified in 45CFR 46.101(b)(1)-(6). The IRB chairperson or his/her designee has the sole authority for determining which UM research falls under these regulations.
- Expedited Review** A review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
- Full Board Review** Research that does not qualify for exempt status or expedited review must be reviewed by the full committee at a convened IRB

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meeting. Meetings dates and times are listed on the IRB webpage.

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## Procedures

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### Scope of Review

The IRB reviews research involving human subjects if one or more of the following apply:

- \* the research is sponsored by UM, regardless of the location of the project;

- \* the research is conducted by, or under the direction of, any staff, faculty, student, or other agent of UM in connection with his or her institutional responsibilities;

- \* the research is conducted by or under the direction of any employee or agent of UM using any property or facility of UM;

- \* the research involves the use of UM's non-public information to identify or contact human research subjects or prospective subjects.

### Levels of Review

**The IRB has the sole authority for determining level of review at the University.**

Research in the **minimal review** category is exempt from

applicable federal regulations, although review by the IRB is still required. Minimal review research must be anonymous and consists of at least one of the following:

- \* commonly accepted educational settings involving normal education practice;
- \* educational tests if the information is taken so that subjects cannot be identified;
- \* (does not apply to children) surveys or interviews that do not deal with sensitive aspects of the subject's own behavior (such as drug use, sexual activity, or criminal activity), or in which the subject's responses would not place the subject at risk of liability, or threaten financial standing or employability;
- \* (needs not be anonymous) surveys or interviews of elected or appointed public officials or candidates for office;
- \* (does not apply to children) observation of public behavior that does not deal with sensitive aspects of the subject's own behavior or in which the subject's responses would not place the subject at risk of liability or threaten financial standing or employability;
- \* collection or study of existing data, documents, records, or biological specimens as long as they are publicly available;
- \* research or demonstration projects of programs under the Social Security Act or other public benefit or service programs;

Research in the **expedited** category is that which poses no more than minimal risk to the subject involving no more than:

- \* collection of hair, nail clippings, baby teeth or teeth in need of extraction;
- \* collection of excreta, sweat, saliva, placenta and amniotic fluid at delivery;
- \* non-invasive recording of data from subjects 18 years of age or older using routine clinical procedures (not including x-rays and microwaves);
- \* collection of blood samples of limited volume and frequency from subjects 18 years of age or older;
- \* collection of dental plaque via routine scaling of teeth using accepted techniques;
- \* voice recordings for research purposes (e.g., of speech defects);
- \* moderate exercise by healthy volunteers;
- \* study of existing data, records, or specimens;
- \* research where the researchers do not manipulate subjects' behavior and the research will not involve stress to subjects;
- \* research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not

required;

Research which is neither minimal nor expedited requires the review of the full IRB.

**Responsibilities of the Researcher** Human subjects protection is a collaborative effort by the researcher and the institution. The researcher/principal investigator is responsible for:

\*submitting all the necessary documents in order to facilitate the IRB's review;

\*the compliance of all co-investigators, student investigators, and research associates with the IRB decisions, conditions, and requirements;

\*reporting to the IRB any changes to the research protocol (e.g., research design of the study, recruitment procedures);

\*requesting re-approval when contact with subjects will extend beyond the approval termination date;

\*reporting to the IRB chair any unanticipated adverse reactions or unanticipated events associated with the conduct of this research;

\*seeking clarification and advice from the IRB regarding ethical aspects of the research.

**Submission and Approval** To submit an application for IRB consideration, go to <http://irb.memphis.edu>.

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**Process**

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**FAQs**

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**Whom do I  
contact for  
additional  
information?**

Please consult the IRB website at [www.memphis.edu/irb](http://www.memphis.edu/irb) for contact information.

**What are the  
educational  
requirements  
associated  
with human  
subjects  
research?**

Researchers, including the faculty advisors of student researchers, must successfully complete online human subjects protection training before submission to the IRB. Details are available online at [www.memphis.edu/irb](http://www.memphis.edu/irb) .

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**Links**

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Title 45 CFR 46, Protection of Human Subjects, U.S. Department of Health and Human Services (DHSS), Office for Human Research Protections (OHRP)

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Title 21 CFR 50, 56, 312, 600 and 812 of the Food and Drug Administration (FDA)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>

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#### **Revision Dates**

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## Institutional Review Board Policies

### 1.01 Exempt Human Research

**Summary/Purpose:** Criteria for classifying exempt research and decision-making processes for IRB review of exempt research.

**Policy:** All research activities involving human subjects under the jurisdiction of the UM IRB will be reviewed, with the exception of certain QA/QI research (see IRB Policy to Exclude Certain Forms of Quality Assurance and Quality Improvement Research from Review).

Some research activities involving human subjects are exempt from the requirement that they receive IRB full or expedited review. The categories of these activities are described in 45 CFR 46.101(b)(1) through (6). Only the IRB may determine which activities qualify for an exempt review. Investigators are not authorized to make this determination and should complete the Exempt application and submit it for the IRB's final determination.

The exemptions provided in 45 CFR 46.101(b) do NOT apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.

Additionally, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does NOT apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed, or research conducted in established or commonly accepted educational settings, involving normal educational practices.

#### 1.1 (a). Investigator Responsibility when Conducting Exempt Research

- a. Research that is determined to be exempt from IRB full board or expedited review is not exempt from protection of the human subjects. The following criteria to protect human subjects must be met for all research involving human subjects:

- b. The investigator must assure that all researchers are trained in the ethical principles, relevant Federal Regulations, and institutional policies governing human subject research using the appropriate CITI course (or approved alternative); a. Exception: Surveys and interviews of adults that the IRB determines to be innocuous require no training.
- c. The investigator must obtain voluntary consent to participate in the research when appropriate (e.g. surveys, interviews) and will provide subjects with pertinent information, i.e. that the activity involves research and has been approved by the IRB. In addition, it may be appropriate to include other information such as contact information for investigators, a description of the procedures, risks and benefits, and IRB contact information.
- d. The investigator must select subjects equitably, so that the risks and benefits of the research are justly distributed.
- e. The investigator must submit any changes to the approved protocol for review and approval before initiating those changes;
- f. The investigator must promptly inform the IRB of any unexpected or adverse events or any complaints from participants; and
- g. The investigator must protect confidentiality and privacy of the subjects and maintain research data appropriately to ensure minimal risk to subjects.

### **Decision-Making Process**

- The following process is used for research that may be exempt from IRB full board or expedited review: The IRB Administrator (IA) or their

designee screens all applications submitted to the IRB for level of review.

- When a protocol does not precisely fit into one of the exempt categories of 45 CFR 46.101(b), the IA consults with the chair of the IRB or the chair's designate.
- The IRB may move a protocol from exempt review to expedited or full board review, even if it meets all relevant exempt review criteria, because of risks, benefits, and other ethical issues.
- A determination that a protocol is exempt from expedited or full board review requires that the research activity meets the criteria for exempt status as outlined in 45 CFR 46.101(b)(1) through (6) and meets the criteria for protection of research participants in exempt research as stated above.

## 1.02 Full Board Review Criteria for IRB Applications

**Summary/Purpose: Criteria and decision-making processes to determine whether IRB applications need Full Board review.**

Introduction: Regulatory criteria for assigning 'exempt' level review are fairly precise. However, in many cases, decisions to assign expedited versus full board review require judgments of risk and interpretation of regulations. This policy is designed to minimize judgment and interpretation and to distribute review level decision-making to a designated sub-group of IRB members under certain conditions.

The regulations allow expedited review when the following two conditions are met: 1) the research involves Minimal Risk and 2) the research is listed as one of the "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure" ([63 FR 60364-60367, November 9, 1998](#)).

**Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests 45 CFR 46.102(i).

Determinations of "minimal risk" and 'minor increase over minimal risk' (for 46.406 research) for children will be based on the attached list [Attachment A] of considerations, criteria, and exemplars that have been conditionally approved by the Department Of Health And Human Services Secretary's Advisory Committee On Human Research Protections (SACHRP).

**Examples of Studies that May Receive Expedited Review**

1. Deception studies using a 'confederate'
2. Deception studies using misleading or deceptive:
  - a. study descriptions
  - b. procedure explanations
  - c. survey instructions / rationales

\*See also **IRB Policy Addressing Deception Research**
3. Subjects are children and research falls under 46.404 "Research not involving greater than minimal risk"
4. Subjects are cognitively impaired and research is approved by an external committee of experts on the population

**Examples of Studies that Likely Require Full Board Review**

- Deception studies that give subjects deceptive feedback, whether positive or negative [e.g., based on IQ or personality tests or interviews]
- Psychotherapy treatment studies with adults
- Studies involving a waiver of parental consent (permission)
- Subjects are in a subservient power relationship to investigators or to parties with an interest in the research, such as employees of the investigator.

**Examples of Elements that Require Full Board Review**

- Administration of alcohol
- Administration of non-drug dietary supplements
- Use of X-rays
- Classified research
- Administration of FDA approved drugs and use of devices presenting more than minimal risk

- Administration of non-FDA approved drugs and devices that come under FDA regulations
- Activity exceeding moderate exercise [See Attachment B for Determination of Intensity of Exercise]
- Surreptitious videotaping in non-public settings
- Surreptitious monitoring of electronic communications
- Subjects are prisoners
- Subjects are pregnant
- Subjects are children and research poses greater than Minimal Risk. Below are the relevant categories.
  - 45 CFR 46.405 "Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects" OR
    - ✓ 45 CFR 46.406 "Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition" OR
    - ✓ 45 CFR 46.407 "Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children"

### 1.03 Expedited or Full Board Review Determination Procedure

- A subcommittee consisting of the IRB Chair and the IRB Administrator, will determine which protocols in categories 1 & 2 above may be reviewed as expedited. Additional Board members will substitute when there is a conflict of interest.
- Vulnerable population studies will be reviewed by an expert consultant(s) if there is no expertise with the population among the subcommittee members. The consultant's review will be considered in the subcommittee's decision-making.

### 1.04 Board Membership

- The Board will maintain at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. The Board will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the Board will be able to ascertain the acceptability of proposed research in terms of University commitments and regulations, applicable law, and standards of professional conduct and practice. The Board will persons knowledgeable in these areas. The Board regularly reviews research that involves vulnerable subjects such as children, prisoners, pregnant women and handicapped or mentally disabled persons, and consideration is given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

- Of these members , one will be a non-scientist , at least one will be a scientist and another will be a member of the community with no University affiliation.
- In order to maintain a Board with knowledge and experience in diverse areas of research, the board maintains at least as many alternate members as members. The alternate members are made up of a radiation safety expert, a licensed medical doctor, a prisoner representative, and faculty researchers with various areas of expertise.
- All members and alternate members are invited to attend all Board meetings. To maintain quorum, half of the member number must be present which includes the Chair and the non-scientist. Protocol reviews are assigned one week prior to Full Board meetings. At that time, it is determined who is required to review, attend, and vote at the meeting. For protocols involving prisoners, the prisoner representative will be assigned to review the protocol, attend and vote at that Board meeting. For protocols involving the use of ionizing radiation, the radiation safety expert and the licensed medical doctor will be assigned to review the protocol, attend and vote at the Board meeting. In the event that meeting attendance surpasses quorum, the minutes note at the beginning of the meeting who is and who is not voting. Alternate members assigned to review protocols due to their areas of expertise will always be designated as voting members at the Board meeting.

## 2.0 Guidance on Determination of Risk

### **DETERMINATION OF MINIMAL RISK FOR CHILD RESEARCH**

Derived from a presentation by: Celia B. Fisher, Ph.D., and Susan Z.

Kornetsky, M.P.H. [5th Report for SACHRP Consideration Clarifying 45 CFR 46 Subpart D Definitions - January 31, 2005](#)

#### **Reference Point for Uniform Definition**

- The definition of "minimal risk" at 45 CFR 46.102(i) when applied to Subpart D should be interpreted as those risks encountered by normal, average, healthy children living in safe environments in daily life or during the performance of routine physical or psychological examinations or tests.

#### **Minimal Risk Should be Age Indexed**

- Evaluation of minimal risk under Subpart D should be indexed to the risks in daily life and routine medical and psychological examinations experienced by children the same age as the subject population.

#### **Upper Limits of Risk & Harm**

- The uniform, age-indexed definition of minimal risk should represent the upper not lower limits of risk to which children can be exposed under §46.404. Rationale: Research procedures should not fall under §46.404 for children who because of health or other reasons would be at greater risk of harm from procedures which are minimal risk for normal, average, healthy children living in safe environments.

#### **Equivalent Procedures**

- Procedures that are equivalent in probability and magnitude of harm to risks of daily life or routine physical or psychological examinations or tests experienced by average, healthy, normal children living in safe environments should be considered as consistent with the definition of "minimal risk."

#### **Equivalence Criteria**

- Is the probability and magnitude of harm equivalent in:

- ✓ duration
- ✓ cumulative characteristics
- ✓ reversibility of harm
- ✓ to risks of daily life or routine examinations

**Examples of Well-Child Procedures [From April, 2005 SACHRP presentation; IOM, 2004; 4.9-4.10]**

- Physical examinations
- Measurement of height, weight, head circumference
- Assessment of obesity with skin-fold calipers
- Collection of blood or voided urine
- Measurement of heart rate and blood pressure
- Hearing and vision tests
- Modest changes in diet or schedule
- Testing of fine and gross motor development
- Non-invasive physiological monitoring
- Medical and social history
- Psychological examinations or tests
- Guidance and education (for the child, the parents, or both)

**Routine Psychological Tests Indexed to Standardized Screening or Assessment Measures**

- Child and adolescent intelligence tests
- Infant mental and motor scales
- Educational tests / Reading and math ability tests
- Neurological or motor disorders
- Social development
- Family and peer relationships
- Emotional regulation
- Feelings of sadness or hopelessness

**DETERMINATION OF MINOR INCREASE OVER MINIMAL RISK FOR CHILD RESEARCH**

Derived from a presentation by: Celia B. Fisher, Ph.D., and Susan Z. Kornetsky, M.P.H. [5th Report for SACHRP Consideration Clarifying 45 CFR 46 Subpart D Definitions - January 31, 2005](#)

**Determining Minor Increase Over Minimal Risk**

- Applying a uniform procedure for assessing whether a research presents a minor increase over minimal risk requires evaluating the risk along 10 different criteria.
- Rationale. Methods, compounds, instruments and other research procedures are so variable that a single quantitative unit of increase cannot be uniformly applied. However, there is a uniform process of evaluation that can be applied.

**List of Uniform Criteria for Determining a Minor Increase Over Minimal Risk**

1. Minimal Risk Comparison
2. Scientific Evidence of Risk
3. Certainty of Evidence
4. Documented Harms
5. Equivalence of Procedures
6. Participant Perspectives
7. Mitigating Factors
8. Inclusion/Exclusion Criteria
9. Monitoring
10. Safety & Competence

**Minimal Risk Comparison**

- The procedure does not meet minimal risk criteria
- The probability and magnitude of harm or discomfort anticipated in the research is greater than those ordinarily encountered by normal, average, healthy children living in safe environments in their daily activities or

during the performance of routine physical or psychological examinations or tests.

## **2. Scientific Evidence of Risk**

- There is peer reviewed scientific evidence of the range of risks associated with the procedure for the subject population, OR
- The procedure is sufficiently similar to other interventions with well characterized risks that prudent, informed judgments about risks can be made.

## **3. Certainty of Evidence**

- The extent and quality of the evidence is such that there is little uncertainty about the range of risks involved.
- Lack of sufficient data for a risk profile would create a higher level of uncertainty supporting a more conservative approach to judgments that a procedure is only a minor increment over minimal risk

## **4. Documented Harms**

- The documented harms are not serious for the subject population
- The data indicates no or an extremely small probability of risk of major complications.
- Harms associated with the procedure do not require in-patient monitoring or follow-up evaluation (for the procedure itself)
- The harms if they occur are transient and reversible

## **5. Transient & Reversible**

- Transient: Restricted to time of procedure or short post-experimental period
- Reversible: Procedure to reverse the effect requires no more than a short-term simple clinical intervention

## **5. Equivalence of Procedures**

- The procedures are equivalent in risk to documented risk profiles in terms of:
  - a. Duration of harm or discomfort and
  - b. Cumulative effect of procedures on the probability and magnitude of harm.

**6. Participant Perspectives**

- Whenever possible the data includes information about the subject population's experience of the procedures (e.g., painful, anxiety producing).

**7. Mitigating Factors**

- The procedure reflects consideration of documented mitigating factors known to minimize or exacerbate the risk.

**8. Inclusion/Exclusion Criteria**

- Subject inclusion and exclusion criteria reflect consideration of documented subject characteristics that may moderate the probability and magnitude of harm of the procedure.

**9. Monitoring**

- There is an adequate monitoring procedure.

**10. Safety & Competence**

- The procedure will be performed in a safe environment by qualified personnel with experience conducting the procedure with the subject population.

## 2.01 DETERMINATION OF INTENSITY OF EXERCISE

### Background

OHRP's "*Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Procedure*" lists under (4)(e) "moderate exercise, muscular strength testing, body composition testing, and flexibility testing where appropriate given the age, weight, and health of the individual." There is no further detail on how to determine what constitutes moderate exercise (versus vigorous exercise). This guidance aims to meet that need.

### Procedure

The "Expedited or Full Board Review Determination Procedure" described above in this policy will be used to decide whether procedures involving exercise meet the definition above. However, for protocols falling into 'gray areas,' three sources of information will be used at the discretion of the 4-member panel:

1. IRB members or others with expertise in medicine and/or exercise science will be consulted.
2. Panel members will have investigators run them through exercise procedures.
3. Panel members will consult the guideline below developed by Dr. Chris Black, exercise physiologist, from the Centers for Disease Control and Prevention and the American College of Sports Medicine.

### ACSM/CDC Guidelines:

- Moderate exercise consists of activities that result in a noticeable increase in breathing and heart rate, but can be comfortably sustained for ~45 minutes. The activities are commonly described as "very light" to "light" to "somewhat hard" when the level of perceived exertion is rated. During moderate intensity exercise, participants should be able to easily carry on a

conversation. Examples of common moderate intensity activities include: o Walking at a moderate or brisk pace on a level surface

o Hiking

o Water aerobics

o Yoga

o Doubles tennis

o Raking the lawn

o Moderate household cleaning (e.g. vacuuming, washing windows, sweeping).

• More than moderate exercise (vigorous) results in substantial increases in breathing and heart rate. The activities are commonly described as "hard" to "very hard" when the level of perceived exertion is rated. Carrying on a conversation is difficult during/while performing vigorous intensity exercise.

Examples of common more than moderate intensity activities include: o Jogging or running

o Step aerobics

o Circuit weight training

o Most competitive sports (basketball, soccer, football, etc.)

o Singles tennis

o Heavy yard work (e.g. digging ditches, swinging an ax, pushing a mower).

• Note: Moderate intensity activities may, in fact, be more than moderate if the participants are sedentary, not physically fit, elderly, and/or have a known cardiac, pulmonary, or metabolic disease.

#### **Reference:**

*ACSM's Guidelines for Exercise Testing and Prescription* (2010).

Baltimore, MD: Lippincott, Williams, & Wilkins.

### 3.0 Education in Human Research Protection

**Summary/Purpose:** Mandatory educational requirement for all individuals involved in human subject research.

Education is a key component of UM's human research protection program. Education includes the knowledge of federal, state, and local laws and regulations, relevant professional standards, and the policies and procedures of The University of Memphis regarding the protection of research participants and the conduct of research. IRB applications will be accepted only when the primary investigator and where applicable their faculty advisor have completed the education requirement.

UM utilizes an online educational program sponsored by the Collaborative IRB Training Initiative (CITI) and hosted by the University of Miami.

Investigators, their faculty advisors, Institutional Review Board (IRB) members, and IRB staff are required to complete the appropriate CITI course for their group and subject population. CITI certification is good for two years. A refresher course must be completed on or before one's two-year anniversary date.

#### **4.0 Identifiable Human Subjects Data Security**

**Summary/Purpose:** Encryption requirements for identifiable and sensitive human subject data. The University of Memphis extends NIH policy (Notice Number: NOT-OD-07-054) regarding data security to all IRB-approved projects.

Researchers are responsible for protecting sensitive and confidential human subject data, and must take reasonable and appropriate action to prevent inadvertent disclosure, release, or loss of sensitive information.

1. All information systems, electronic or hard copy, that contain sensitive data must be protected from unauthorized access.
2. PIs should avoid housing subjects' sensitive information on portable storage devices.

#### **Sensitive Information**

Sensitive information is any information recorded in such a manner that subjects can be identified, either directly or through linked identifiers, or information which, if disclosed, could place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Sensitive information includes but is not limited to:

- mental health survey or interview data
- sexual behaviors
- illegal drug use
- medical diseases
- financial information

#### **Non-sensitive information might include:**

- attitude data
- personality survey data
- health behaviors
- human performance data

### **Portable Devices**

If portable storage devices must be used, the data should be encrypted. These devices include but are not limited to:

- laptop computers
- personal digital assistants
- cell phones
- pocket or portable memory devices such as thumb, jump, and flash drives
- CDs and DVDs

### **Non-Portable Devices**

Non-portable devices (i.e., desktop computers) must have proper access controls such as strong password protection.

### **Transmitting Research Data Electronically**

Research data should be transmitted only when the security of the recipient's systems is known.

### **Guidance on & Requirements for Data Encryption**

Free, user-friendly encryption software, recommended by IT is available at <http://www.truecrypt.org/>

Encryption requires creation of a password and/or certificate to access your encrypted data (see user instructions on website). Loss of those access keys means data can never be recovered. If human subjects data are lost, the cost-benefit ratio weighed in IRB reviews is swayed due to zero benefit from new knowledge. Therefore, to reduce the likelihood of such loss, the following data back-up requirements must be met for data encryption:

If data are encrypted on a portable device, there must be a second copy of the data either on

1. A desktop [password protected and secured, but not necessarily encrypted]
2. A second portable device that is also encrypted, but using a different password/certificate

## 5.1 IRB Policy to Exclude Certain Forms of Quality Assurance and Quality Improvement Research from Review

**Summary/Purpose:** Lists certain types of human subjects research that do not require IRB review or applications.

- All human subjects research requires an application to the IRB
- Quality assurance / quality improvement (QA/QI) could be considered research by the
  - federal regulations
  - The IRB has determined that certain forms of QA/QI activities do not require IRB review or applications:
    - Teaching, Faculty and Staff evaluations (However, research on such evaluations *would* require IRB review)
    - Performance evaluations
    - Institutional program review
    - Classroom assessment
    - Curriculum review
    - Strategic planning

Investigators unsure of whether their research must be reviewed by the IRB should inquire at the IRB office, [irb@memphis.edu](mailto:irb@memphis.edu)

## 5.2 WAIVER OF IRB APPLICATION FOR CLASS PROJECTS

**Summary/Purpose:** To offer instructors who assign class projects using humans as subjects an alternative to requiring each student to submit an IRB application.

It is the University of Memphis IRB's policy to review all research conducted by faculty, staff, and students. The IRB must determine if studies meet the Code of Federal Regulations definition of "Research," which requires a formal IRB determination.

Many class-assigned projects using humans as subjects do not meet the criteria in the federal definition of research (i.e., "*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*"). In some of these cases, classroom projects may not require an IRB application.

**To minimize administrative burdens on instructors and students, the IRB offers instructors an alternative to requiring each student to submit an IRB application, provided that:**

1. **Publication or presentation outside of the University of Memphis.** Data obtained from this class project **CANNOT** be used for publication, presentation at a professional meeting, or used in thesis/dissertation research.
2. Data collected will be used to satisfy a class assignment **only**. The data will not be shared outside the University. The data will not be used in a student's **Master's Thesis, Doctoral Dissertation, Capstone project, or equivalent graduation requirements.**

#### **Students as PIs in Human Subjects Research**

**Summary/Purpose:** Defining the role of students as principal investigators on research projects involving human subjects. UM undergraduate and graduate students may serve as principal investigators (PIs) on research projects with human subjects, but they must have a UM faculty member as a research advisor on the project.

### 5.3 RESEARCH IN SCHOOLS AND ORGANIZATIONS HAVING NO IRB

**Summary/Purpose:** Additional requirement for researchers conducting research in schools and organizations that have no IRB.

Researchers conducting research at organizations (e.g., school district, hospital, mental health facility, business, sports team, or other organization) which have no IRB must obtain permission from appropriate authorities at the organization. Documentation of permission should be provided to the UM IRB.

*\*See policy on Collaborative and Biomedical Research Review for organizations that have an IRB.*

### 5.4 External Investigators Conducting Human Subjects Research at UM

**Summary/Purpose:** IRB review authority for research conducted at UM by investigators external to the University.

#### **Introduction**

This policy addresses human subjects investigators from other institutions who access UM faculty, staff, and students to participate as subjects in their research and aims to ensure protection of UM personnel to the extent possible.

#### **Policy**

Investigators external to UM must have their research reviewed by the UM IRB, unless they solicit research subjects solely through public means (e.g., posters on public bulletin boards (see the UM policy on where flyers may be placed), email addresses obtained from the UM web site) and with no assistance of any UM personnel office.

## 5.5 Collaborative and Biomedical Research Review

**Summary/Purpose:** IRB review authority and procedures for collaborative and biomedical research.

### Introduction

This policy covers two situations, which often overlap. First, it sets policy for research collaborations, broadly defined as UM investigators conducting research at other research institutions, including subcontracting such work. Second, it covers IRB review of biomedical research, such as trials of FDA approved drugs and devices presenting more than minimal risk or drugs and devices not FDA approved. Because UM's IRB is constituted to expertly review social/behavioral research and not biomedical research, biomedical research requires review by an alternative IRB that has that expertise.

### Policy

- Social/behavioral research conducted by UM faculty/staff/students at another institution will be subject to review by UM's IRB. These investigators must ask the local institution's IRB if it wishes to review the research and must provide written evidence to the UM IRB of either local IRB approval or that the local IRB declined review.\*
- The review of biomedical research 1) that is conducted by UM researchers at UM, 2) that is conducted by UM researchers at a collaborating research institution, or 3) that is subcontracted from UM will be deferred to the collaborating or subcontracted institution's biomedical IRB. The latter will require an authorization agreement between both institutions and modification to UM's Federal-wide Assurance with the Department of Health and Human Services' Office of Human Research Protections.

A collaborating institution's IRB will:

- Provide copies to UM's IRB on any

1. reports of
  - a) adverse events or
  - b) unanticipated problems involving risks to participants or others
2. Progress/renewal reports
3. Other correspondence related to the approved research.

UM's IRB reserves the right to conduct a site visit of the research (after obtaining approval from the collaborating institution's IRB and any other authority required).

\*See policy on Research in Schools and Organizations Having No IRB for institutions with no IRB.

## 6.0 IRB Policy Addressing Deception Research\*

**Summary/Purpose:** Criteria for classifying deception research and decision-making processes for IRB review of deception research.

### Definition for Deception

*"Deception is defined as the deliberate attempt, whether successful or not, to fabricate, and/or manipulate in any other way, factual and/or emotional information, by verbal and/or nonverbal means, in order to create or maintain in another or others a belief that the communicator himself or herself considers false."*

Source: Masip, J., Garrido, E., and Herrero, C. (2004). Defining deception. *Anales de Psicología*, 20, 147-171. [Modified definition]

### Deception Elements that Trigger Full Board Review [because of increased risk]

- Surreptitious videotaping

### Deception Elements that Likely Require Full Board Review [because of increased risk]

- Giving Subjects deceptive feedback, whether positive or negative [e.g., based on IQ or personality tests or interviews]

### Deception Elements that May Receive Expedited Review [because of lower risk]

- Use of a 'confederate'
- Misleading or deceptive:
  1. study descriptions
  2. procedure explanations
  3. survey instructions / rationales

**American Psychological Association*****Ethical Principles of Psychologists and Code of Conduct, 2002*****8.7 Deception in Research**

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

(b) Psychologists do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.

(c) Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

**8.8 Debriefing**

(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.

(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.

(c) When psychologists become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

**Federal Regulations: 45CFR46.116 [Waiver of some or all elements of consent]**

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

## 6.1 Certificates of Confidentiality

**Summary/Purpose:** Criteria for requiring Certificates of Confidentiality to add protection for sensitive human research.

### Background and Applicability

(from NIH at <http://grants1.nih.gov/grants/policy/coc/faqs.htm> )

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research.

Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for a Certificate.

**Sensitive information** includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.

### Studies eligible for a Certificate (partial list):

- Research on HIV, AIDS, and other STDs;
- Studies that collect information on sexual attitudes, preferences, or practices;

- Studies on the use of alcohol, drugs, or other addictive products;
- Studies that collect information on illegal conduct;
- Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community;
- Research involving information that might lead to social stigmatization or discrimination if it were disclosed;
- Research on participants' psychological well being or mental health;
- Genetic studies, including those that collect and store biological samples for future use;
- Research on behavioral interventions and epidemiologic studies.

**Studies ineligible for a Certificate:**

- not research based,
- not approved by an IRB in accordance with these guidelines,
- not collecting sensitive information or information that might harm the research participants, or
- not collecting personally identifiable information.

**Identifying characteristics** include things such as: name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research participant which could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject.

## 6.2 UM Policy When Certificates of Confidentiality are Required

The IRB generally limits *requiring* researchers to get Certificates to studies where there is a real risk of a subpoena or court order to produce data and where identifying information is retained for a significant period of time.

- The IRB will require a Certificate in studies collecting admissions of criminal activity. These include studies on rape and illicit drug use, for example.
- Certificates will generally not be required for data that could be socially stigmatizing, because these are less likely to be solicited by the legal system. Researchers may opt to get Certificates without IRB mandate. Because Certificates require altered consent forms, the IRB must be made aware of Certificates obtained by researchers, and consent forms must comply with NIH requirements before IRB will approve them.

## 7.1 Determination of Post-Approval Review Interval

**Summary/Purpose:** This policy specifies conditions and procedures for determining post-approval review intervals. Most UM human subjects studies pose minimal risks to subjects. Therefore, the post-approval time interval for IRB progress reports is commonly one year, the maximum interval allowed by the regulations at 45CFR46.109(e), and a standard reporting form is used. However, additional reporting may be necessary:

1. The IRB requires more frequent progress reports, including observations by the IRB or a third party of the consent process and the research, when deemed necessary to monitor or further assess risk following protocol approval.
2. The IRB may require more frequent reports either at regular intervals or after small subsets of subjects are exposed to study procedures.
3. Reporting requirements may be altered during the course of a study based on new information.
4. Reports will be tailored to studies.

Circumstances that may require more frequent progress reports include, but are not limited to, the following:

- ✓ A researcher's history of noncompliance with federal regulations or IRB requests
- ✓ research procedures with high or unknown risks, particularly with vulnerable subjects
- ✓ complaints from subjects or others
- ✓ unexpected adverse events occurring during the course of the study

Investigators will be informed of reporting requirements in the approval letter. Adjustments to initial reporting requirements will be determined by IRB Administration (IRB Chair, IRB Administrator and Vice Provost for Research) in consultation with the full IRB if deemed advisable.

## 8.0 Course Requirements or Credits for University of Memphis Students to Participate as Research Subjects

**Summary/Purpose:** Course syllabi cannot mandate or unduly influence research subject participation.

Student participation as research subjects must be completely voluntary. If a syllabus specifies that participation is a course requirement and/or extra credit is offered for participation, ***students must be given alternatives*** that involve comparable time and effort in order to minimize possible undue influence on the decision to participate. Students must not be penalized for refusing to participate in research.

## 9.1 Use of Human Tissue and Commercially Available Human Cell Lines

**Summary/Purpose:** To explain the criteria for the review of research using human tissue and commercially available cell lines.

### Studies that do not require IRB Review

- **Policy:** Studies using human tissue where donors cannot be identified or commercially available human cell lines are not human subjects research and do not require IRB review.
- **Regulations:** According to the Office for Human Research Protections (OHRP), "HHS conducted or supported research that involves neither interactions nor interventions with living individuals or obtaining identifiable private information is not considered human subjects research. Accordingly, *in vitro* research and research in animals using already derived and established human cell lines, from which the identity of the donor(s) cannot readily be ascertained by the investigator, are not considered human subject research and are not governed by the HHS or FDA human subject protection regulations appearing at 45 CFR Part 46 and 21 CFR Parts 50 and 56. IRB review is not required for such research." [Office for Human Research Protections Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles, March 19, 2002.]

**Studies that require IRB Review**

- **Policy:** Investigators who wish to conduct research using human tissue OR human cell lines where the donor(s) may be identified must submit an IRB application for review and approval prior to beginning their research.
- **Regulations:** OHRP also notes, "HHS-conducted or supported research that uses human cell lines where the donor(s) may be identified, including cells that retain links (such as a code) to identifying information is generally considered human subject research that is governed by 45 CFR Part 46 because the donors are human subjects. IRB review and approval is required for such research." [Office for Human Research Protections Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles, March 19, 2002.]

## 10.0 Conflict of Interest and IRB Protocol Review

**Summary/Purpose:** Defining conflicts of interest involving IRB members, alternates, staff, and consultants.

**Policy:** Federal regulations prohibit a member of the Institutional Review Board (IRB) from participating in the initial or continuing review of any protocol in which the member has a conflict of interest (COI), except to provide information at the IRB's request (45 CFR 46107(e)). This policy: (1) extends exclusion of individuals with COIs to review of revisions, unanticipated problems involving risk to subjects or others, non-compliance investigations, or suspension/termination decisions, (2) extends exclusion coverage to consultants (*ad hoc* reviewers who are not IRB members but sometimes are asked to review a project because of their expertise), and (3) defines and gives examples of COIs.

IRB Committee Members, alternate members, consultants, and IRB staff are considered to have a COI if they have any: (a) significant financial interest as defined below; (b) significant role in the conduct of the research; or (c) other COI including having an immediate family member as an investigator on an IRB protocol.

### **Definitions:**

**Conflict of Interest** is any situation which involves a financial interest, other opportunity for tangible personal benefit, or a personal relationship that could affect the reviewer's impartiality.

**Significant Financial Interest:** Anything of monetary value, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, board member, executive relationship, or other ownership interests); and intellectual

property rights (e.g., patents, trademark, licensing agreements, copyrights and royalties from such rights).

**Immediate Family Member:** Immediate family includes spouse or domestic partner, all dependent children (stepchildren, biological children, wards), siblings, parents, and guardians.

**Significant Role in the Conduct of Research:** Service as a Principal or Co-Investigator, a supervisory role over the Principal Investigator, chair of a thesis or dissertation committee, and member of a thesis or dissertation committee where a significant benefit is likely (e.g., publication authorship

**Examples of COIs:**

- An application includes an investigator or research staff who is a spouse or relative of the reviewer
- A thesis or dissertation application for which the reviewer is a member of the thesis or dissertation committee if publication or presentation authorship is likely
- An IRB member is an investigator on a project
- An IRB member (or immediate family) has or will receive from the sponsor of the research financial or other forms of compensation
- An IRB member (or immediate family) has a significant financial interest in the company/agency/firm that is sponsoring the research
- An IRB member (or immediate family) discloses a conflict of interest to the FDA or other agency.

**Full Board Review Procedures:**

1. Chair asks if anyone has a COI to declare.
2. Any member with a COI must leave the room during the discussion of the protocol and the related vote. However, they may provide information at the IRB's request.
3. While recused, the member will not count towards the quorum, and the meeting minutes will document the temporary recusal.

4. Consultants who declare a COI will be excused from the review of the protocol and the IRB will identify another consultant with the relevant expertise.

**Expedited or Exempt Review Procedures:**

1. The IRB Administrator or Chair declares a COI.
2. The protocol is assigned to another board member for review.
3. Consultants who declare a COI will be excused from the review of the protocol and the IRB will identify another consultant with the relevant expertise.

## 11.0 Adverse Events and Unanticipated Problems

**Summary/Purpose:** This policy describes the process that the IRB follows to deal with reports and findings of adverse events and unanticipated problems in research studies.

### Definitions:

**Adverse Event:** Any undesirable effect (unfavorable physical or psychological harm) occurring in a human subject, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Examples include but are not limited to an abnormal physical exam or laboratory finding, unusual symptoms or occurrence of disease, and psychological reactions such as intense sadness or transient anxiety.

**Serious Adverse Event:** An adverse event that results in any of the following: death, hospitalization, significant disability, congenital anomaly or birth defect, a life-threatening situation, or concerns about the physical health or future health of the subject.

**Unanticipated Problem:** An incident or experience occurring during the course of research that meets all of the following criteria:

- Is not described in the protocol or consent form or is unexpected in nature, severity, or frequency;
- May possibly be related to participation in the research; and
- Suggests that the research places subjects or others at a greater physical, psychological, economic, or social risk of harm than was described in the consent form or protocol.

***Prompt Reporting of Unanticipated Problems or Adverse Events:***

- Unanticipated Problems that are serious adverse events should be reported to the IRB within 1 week of an investigator becoming aware of the event or effect.
- Any other Unanticipated Problems should be reported to the IRB within 2 weeks of an investigator becoming aware of the incident or experience.
- The form to be used when reporting incidents or events to the IRB is the Unanticipated Problems Involving Risks to Subjects or Others/Adverse Events form.

**Process for Handling Reports of Unanticipated Problems or Adverse Events:**

1. A report of an Unanticipated Problem or Adverse Event is sent to the IRB Administrator or the IRB Chair.
2. The IRB Executive Committee determines whether the report involves an Unanticipated Problem, an Adverse Event, or both. This committee will be composed of the Board Chair, the IRB Administrator and one other member or alternate member of the IRB. For each occasion when this committee meets, the Board chair will identify from among the IRB members or alternate members a person to serve on this committee. Selection will be based on availability and/or needed expertise. If the Executive committee member reports a potential conflict of interest, that Committee member will be replaced by another IRB member or alternate member.
3. The IRB Executive Committee may notify the Full IRB at any time during the process of examining reports of unanticipated problems or adverse events. All events and final outcomes will be reported to the Full IRB at the regular monthly meetings.

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4. If the report is determined to be an Adverse Event, but not an Unanticipated Problem, further reporting to appropriate institutional officials, the department or agency head (or designee), and OHRP is not required under HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5).

5. If the report is determined to be an Unanticipated Problem, whether Adverse Event or not, the IRB must promptly (within one month) report the incident, experience, or outcome to appropriate institutional officials, any supporting

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department or agency head (or designee), and OHRP. The types of actions that the IRB may consider taking for any event include, but are not limited to:

- Acknowledgement/acceptance without further recommendation;
- A request for further clarification from the investigator;
- Modification of the research protocol or procedures;
- Modification of the consent/assent process or consent/assent form;
- Providing additional information to current and past research participants;
- Additional monitoring of the research protocol or consent process;
- Education for the investigator or research staff;
- Limitations on the research activities;
- Suspension or termination of the research.

6. The IRB will notify the investigator upon receipt of the report as well as after a decision has been made regarding actions to be taken (including acknowledgement/acceptance without further recommendation).

7. If the investigator has concerns regarding the actions to be taken, he may submit these to the IRB in writing for consideration.

8. A follow-up report detailing the outcome of any event (whether unanticipated problem or adverse event) may be submitted to appropriate institutional officials, any supporting department or agency head (or designee), OHRP, and the full IRB.

#### **Student Subject Pool Adverse Events**

1. Subject pool administrators are required to report any complaints involving human subject research to IRB Administration within 3 business days of the complaint being reported to them. The steps listed above will be employed to investigate and resolve any issues relating to student subject pool participants rights.

### 11.1 Non-Compliance with Human Subject Protection Regulations

**Summary/Purpose:** This policy describes the process that the IRB follows to deal with allegations and findings of non-compliance with human subject protection regulations and guidelines.

**Definitions:**

**Allegation of Non-compliance:** A disclosure of possible non-compliance with human subject protection regulations.

**Complainant:** Person reporting a non-compliance.

**Continuing Non-compliance:** A pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, indicates a lack of understanding of the regulations or institutional requirements that may affect the rights and welfare of participants, should have been seen as compromising the scientific integrity of a study (such that important conclusions could no longer be reached), suggests that non-compliance will continue without intervention, or consists of frequent instances of minor non-compliance. Continuing non-compliance also includes failure to respond to a request for information or for actions to resolve non-compliance with human subject protection regulations.

**Minor Non-compliance:** Non-compliance that is neither serious nor continuing. An example of minor non-compliance includes failure to comply with UM IRB administrative policies (for example, turning in a progress report late, using a consent form lacking the IRB approval stamp, or failing to submit an IRB application for a study later determined exempt).

**Non-compliance:** Any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with

federal regulations or the requirements or determinations of the IRB. Non-compliance actions may range from minor to serious, be unintentional or willful, and may occur once or more than once. The degree of non-compliance is evaluated on a case-by-case basis and will take into account such considerations as to what degree subjects were harmed or placed at an increased risk and the willfulness of the noncompliance. Examples include, but are not limited to: Failure to obtain IRB approval; inadequate or non-existent procedures for the informed consent process; inadequate supervision; failure to follow instructions from the IRB; failure to report adverse events or protocol changes; or protocol deviations.

**Serious Non-compliance:** An action or omission in the conduct or oversight of research that affects the rights and welfare of participants, increases risks to participants, decreases potential benefits, or compromises the integrity or validity of the research. Examples of serious non-compliance include, but are not limited to: Conducting non-exempt research without IRB approval; enrollment of subjects who fail to meet inclusion or exclusion criteria of a protocol that increases the risk to the subject; enrollment of research subjects while study approval has lapsed; or major protocol deviations that may place subjects at risk from the research.

**Reporting Allegations of Non-compliance:**

Allegations of non-compliance may come to the attention of the IRB in several ways, including but not limited to:

- New applications or continuing reviews submitted to the IRB;
- Post-approval monitoring;
- Reports from collaborators, employees, participants, family members, community members;
- Complaints from anonymous sources.

Allegations of non-compliance should be reported to the IRB Administrator ("IA") or Chair. Allegations should include a detailed description of the non-compliance, the name of the Principal Investigator listed on the IRB protocol, and, if known, the title and number of the protocol. Complainants will be protected from repercussions as per University policy.

**Process for Handling Allegations of Non-compliance:**

1. An allegation of non-compliance is reported the IA or the IRB Chair, who performs the investigation along with the other members of the IRB Executive Committee (the IRB Coordinator and designated board members)
2. The Executive Committee determines whether the allegation has a basis in fact. If the allegation is serious, the Executive Committee may convene the IRB to consider suspending the research while investigating the allegation. If the allegation is serious, and the noncompliance is evident from the facts, the Executive Committee may suspend the research.

**Investigation may include but is not limited to:**

- a. Informing the Principal Investigator of the allegation and requesting a response (mandatory);
  - b. Interviewing members of the research team, complainant, and/or subjects;
  - c. Conducting an unannounced laboratory visit;
  - d. Reviewing research records.
3. If the allegation is determined to have a basis in fact, the Executive Committee classifies the non-compliance as serious, continuing, or neither serious nor continuing.

4. If the non-compliance is determined to be neither serious nor continuing, the Executive Committee may decide what actions to take, and report the outcome to the full IRB at the next convened meeting.

5. If the non-compliance is determined to be serious or continuing, or if the categorization is not clear, the finding is brought to the IRB at a convened meeting for consideration of actions to be taken. Findings of serious or continuing non-compliance are reported to OHRP, supporting agencies, and institutional officials as appropriate.

**Process for Handling Non-compliance Determined to be neither Serious nor Continuing:**

1. The Executive Committee discusses what actions will be taken, and reports these actions to the IRB at the next convened meeting. These actions may include but are not limited to:

- a. Sending a letter of reprimand to the Principal Investigator (copied to department chair, dean, institute director, or center director);
- b. Educating the investigator, department, institute, center, or staff.

2. If the Executive Committee cannot agree on actions to take, the non-compliance will be reviewed at the next convened meeting of the IRB.

**Process for Handling Non-compliance Determined to be Serious or Continuing:**

1. The Institutional Official is informed and consulted.
2. The non-compliance is reviewed at a convened meeting of the IRB.
3. The following information is distributed to the IRB:
  - a. Title and abstract of the research project and/or grant proposal in which the non-compliance occurred;
  - b. Name of the Principal Investigator on the protocol;

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- c. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement); and
  - d. A detailed description of the non-compliance.
4. The IRB discusses what actions will be taken. These actions may include but are not limited to:
- a. Educating the investigator and/or all research staff;
  - b. Suspending the protocol;
  - c. Suspending all protocols of the investigator (temporarily or permanently);
  - d. Conducting random audits of the investigator and/or all research staff;
  - e. Modifying the protocol;
  - f. Obtaining information from other organizational entities (e.g., legal counsel, Institutional Official).
5. The Executive Committee reports a summary of the non-compliance and the action(s) taken or in progress to OHRP, supporting agencies, the IRB, and institutional officials as appropriate.

## 11.2 Post Approval Monitoring (PAM)

**Summary/Purpose:** This policy describes procedures for Post Approval Monitoring of protocols. The purpose of PAM is to ensure that protocol activity remains compliant with appropriate regulations and to improve the quality of research by detecting errors and/or omissions to be corrected.

**Procedures:**

1. The IRB Executive Committee (EC) will select protocols for PAM based on the following criteria:
  - a. Random selection utilizing the IRB protocol database;
  - b. Protocols with history of noncompliance with federal regulations or IRB requests;
  - c. Protocols that have had numerous adverse incidents;
  - d. Protocols involving greater than minimal risk;
  - e. Protocols involving vulnerable subject populations; and
  - f. Protocols from new Principal Investigators (PIs).
  
2. When a study has been chosen for PAM, a letter of notification will be sent to the PI with a request for a mutually agreeable date and time to meet with the PI and any available research personnel. The letter will also include areas and records to be examined.
  
3. The EC will assign EC and/or IRB members to conduct the PAM visit.
  
4. The PAM team will review the protocol file, including informed consent and assent forms, CITI human subjects protection training, etc. prior to the visit.
  
5. Areas examined during a PAM visit include but are not limited to:
  - a. Adherence to protocol;

- b. IRB documentation (e.g., approval letter, protocol, subject recruitment materials);
  - c. Signed and dated consent and assent forms;
  - d. Subject study records and data (e.g. confidentiality, number of subjects matches consent forms);
  - e. Correspondence with the IRB;
  - f. Unanticipated problems or adverse events documentation (if applicable);
  - g. Annual Progress Reports;
  - h. Data management/storage system (e.g. locked cabinet, data encryption);
  - i. Changes to the original protocol and applicable amendments.
6. At the conclusion of the PAM visit, the team will discuss findings directly with the PI.
7. Actions after a PAM visit include, but are not limited to:
- a. Acknowledgement/acceptance without further recommendation;
  - b. A request for modification of the research protocol or procedures;
  - c. A request for modification of the consent/assent process or consent/assent form;
  - d. Providing additional information to current and past research participants;
  - e. Scheduling an additional PAM visit after a predetermined period of time;
  - f. Education for the investigator or research staff;
  - g. Limitations on the research activities;
  - h. Suspension or termination of the research
8. A report detailing the findings and the outcome of a PAM visit will be sent to the PI, the PI's chair or director, the full IRB, and institutional officials as appropriate.

## 12.0 Third Party Research

**Summary/Purpose:** Definition of third party research and determination of need for informed consent of third parties.

### **Definitions:**

**Third party research:** Information provided by a human subject about someone else (i.e., a third party) who has no interaction with the researchers.

**Human subject:** When the information is private and the third party can be readily identified by the information, he/she is considered a human subject and must give informed consent to participate.

**Private information:** "...information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (45 CFR 46.102)."

**Identifiable information:** "...the identity of the subject is or may readily be ascertained by the investigator or associated with the information (45 CFR 46.102)," e.g., social security number, identifiable photographic images, etc. Familial or social relationships alone, i.e. mother, father, etc., are not considered identifiable information.

### **Procedure:**

The IRB determines who is a human subject (and thus must give informed consent) by considering the following four factors (among others):

- The quantity of information collected about the third party;
- The nature of the information collected, including the sensitivity of the information and the possibility that it might harm the third party;

- The ability of investigators to record information on third parties in a manner that protects the identity of those parties; and
- The possibility that classification of a third party as a human subject may have an impact on the rights or welfare of the originally designated human subject, which obligates the IRB to protect the interests of both the original human subject and the third party.

\*See also: Protection of Third Party Information in Research: Recommendations of the National Institutes of Health to the Office for Human Research Protections ([http://bioethics.od.nih.gov/nih\\_third\\_party\\_rec.html](http://bioethics.od.nih.gov/nih_third_party_rec.html))

### 13.1 Snowball Recruiting

**Summary/Purpose:** Definition of snowball recruiting, it's possible complications, and requirements for researchers.

**Definition of snowball recruiting:** Also called peer or network recruiting, snowball recruiting involves asking currently enrolled or potential research participants to recruit additional participants with similar attributes or qualities as those being studied.

**Types of recruitment:** Recruitment can happen in one of two ways.

1. A participant in a study can nominate someone by giving information to the investigator (who then contacts the nominee); or
2. A participant in a study can nominate someone by giving him/her information about the study and having the nominee contact the investigator.

**Possible complications:**

- A participant being recruited by a person in a position of authority may feel undue influence to participate in the research study because of the status of the nominator.
- Recruitment for studies involving sensitive subject matters or potentially embarrassing information *may* cause more than minimal risk to participants.
- Sensitive subject matters include but are not limited to medical or psychological diagnoses, illegal behavior, or sexual orientation.
- Subject matters such as occupation, leisure activities, or age likely do not involve increased risk to participants. See Third Party Research policy for more information.

**Requirements:**

- Type 1 recruitment:
  - a. Researchers should ask participants whether they would be willing to nominate potential participants to complete the study. This script must be included with the IRB application.
  - b. Researchers should obtain a nominating participant's consent to reveal the participant's identity to nominees.
- Type 2 recruitment:
  - a. Researchers should ask participants whether they would be willing to pass on some information about the study to other potential participants. This script must be included with the IRB application.
  - b. Researchers should give participants an information sheet that they can pass on to people they think may be qualified and interested in participating in the study. This information sheet must be included with the IRB application.
- ***For all snowball recruitment strategies***, researcher should make sure participants are aware that they do not have to recruit anyone and will not be penalized for declining to do so. This script must be included with the IRB application.

#### 14.0 Researcher as Participant

**Summary/Purpose:** Procedure when the researcher is also a research participant. Principal investigators may serve as their own research participants and are not subject to the IRB application and review process. If other subjects are involved, standard procedures apply.

### **15.0 Incorporation of Procedures Into this Policy**

All IRB procedures captured in the IRB Initial Review Request and Subsequent Event guidelines are herein incorporated by reference to this policy manual.