

Walsh University  
IRB Policy and Procedure  
Manual Part I

**Approved:**  
**Faculty Senate 12/06/2013**  
**Updated 09/02/2015**

# Walsh University IRB Policy and Procedure Manual

## Table of Contents

### **PART ONE: Institutional Review of Research at Walsh University**

#### **Section 1: Introduction**

- 1.1 Background Information
- 1.2 Mission
- 1.3 Institutional Commitment
- 1.4 Human Subject Research Oversight (organizational structure)
- 1.5 Purpose and Scope of the Manual
- 1.6 Applicability
- 1.7 Revision and Maintenance of the Manual

#### **Section 2: Definitions**

- 2.1 Definitions Applicable to All Sections of this Manual

#### **Section 3: General Policies and Procedures**

- 3.1 Applicable Regulations and Laws
- 3.2 Institutional Review Board
  - 3.2.1 Purpose
  - 3.2.2 Designation and Authority
  - 3.2.3 Composition and Appointment of the IRB
- 3.3 Term of Appointment
- 3.4 Committee Officers
- 3.5 Meetings
- 3.6 IRB Meeting Minutes
- 3.7 Confidentiality of the Review Process
- 3.8 Conflict of Interest
  - 3.8.1 IRB Members – Convened Meeting
  - 3.8.2 Designated Reviewers for Expedited Review
  - 3.8.3 Examples of IRB Member COI
  - 3.8.4 Principal Investigator (PI)/Researcher
- 3.9 Training Requirements
  - 3.9.1 Principal Investigators/Researchers
  - 3.9.2 IRB Members
- 3.10 Roles and Responsibilities
  - 3.10.1 Principal Investigators/Researchers
  - 3.10.2 Student Research Advisors
  - 3.10.3 Institutional Official
  - 3.10.4 Institutional Review Board
  - 3.10.5 IRB Chair and Vice Chair
  - 3.10.6 IRB Members
  - 3.10.7 IRB Administrator
  - 3.10.8 IRB Administrative Assistant

#### **Section 4: IRB Review and Approval of Research Activities**

- 4.1 Governing Principles/Regulations
- 4.2 Exempt Research
  - 4.2.1 Exempt Research
  - 4.2.2 Criteria to Determine that Subjects of Exempt Research are Protected
  - 4.2.3 Length of Approval Period

# Walsh University IRB Policy and Procedure Manual

- 4.2.4 Modifications to Exempt Research
- 4.2.5 Notification of Determination: Exempt Research
- 4.3 Expedited Review
  - 4.3.1 Submission and Review Schedule
  - 4.3.2 Submission Requirements/Materials Reviewed
  - 4.3.3 Assignment of Expedited Reviewer
  - 4.3.4 Reviewer Considerations
  - 4.3.5 Applicability Criteria
  - 4.3.6 Criteria for IRB Approval of Research
  - 4.3.7 Scientific/Scholarly Review
  - 4.3.8 Length of Approval Period
  - 4.3.9 Reporting of Expedited Review to the IRB
  - 4.3.10 Notification of Determination: Expedited Review
- 4.4 Full IRB Review
  - 4.4.1 Submission and Review Schedule
  - 4.4.2 Data and Safety Monitoring Plans
  - 4.4.3 Assignment of Primary and Secondary Reviewers
  - 4.4.4 Distribution of Submitted Materials to IRB Members
  - 4.4.5 IRB Meeting Schedule
  - 4.4.6 Presentation and Discussion of Protocols
  - 4.4.7 Criteria for IRB Approval of Research
  - 4.4.8 Scientific Review
  - 4.4.9 Length of Approval Period
  - 4.4.10 Notification of Determination: Full Board Review
- 4.5 Possible IRB Protocol Determinations
- 4.6 Final Approval and Expiration Dates

# Walsh University IRB Policy and Procedure Manual

## Section 1: Introduction

### 1.1 Background Information

Walsh University (formally, Walsh College) was founded on November 17, 1960, when the seven founding Brothers of Christian instruction, who comprised the entire faculty, welcomed the incoming class of sixty-seven. Initially, Walsh College offered a liberal arts curriculum with majors in secondary education and business administration, as well as pre-professional programs in dentistry, medicine and law. Today, Walsh University's nearly 3,000 students can select from more than 50 undergraduate majors and seven graduate degrees including a doctorate of physical therapy and a doctorate of nursing practice.

Concomitant with the growth in programs has been Walsh University's commitment to and expansion of research opportunities for faculty and students. The expansion of research sponsored under Walsh's human ethics review board has facilitated the need for a full institutional review board (IRB). The IRB is responsible for providing guidance and oversight for the human participant protection program and for helping to maintain compliance with applicable laws, regulations, and policies. The IRB performs human research protection functions not only for Walsh but also for other community-based organizations that may affiliate in human subject's research with Walsh University.

### 1.2 Mission

Walsh University is an independent, coeducational Catholic, liberal arts and sciences institution. Founded by the Brothers of Christian Instruction, Walsh University is dedicated to educating its students to become leaders in service to others through a values-based education with an international perspective in the Judeo-Christian tradition.

Walsh University believes in the desirability of a small university that promotes academic excellence, a diverse community and close student-teacher interactions. The University provides its students a higher education that fosters critical thinking, effective communication, spiritual growth, and personal, professional and cultural development. Walsh University encourages individuals to act in accordance with reason guided by the example and teachings of Jesus Christ.

### 1.3 Institutional Commitment

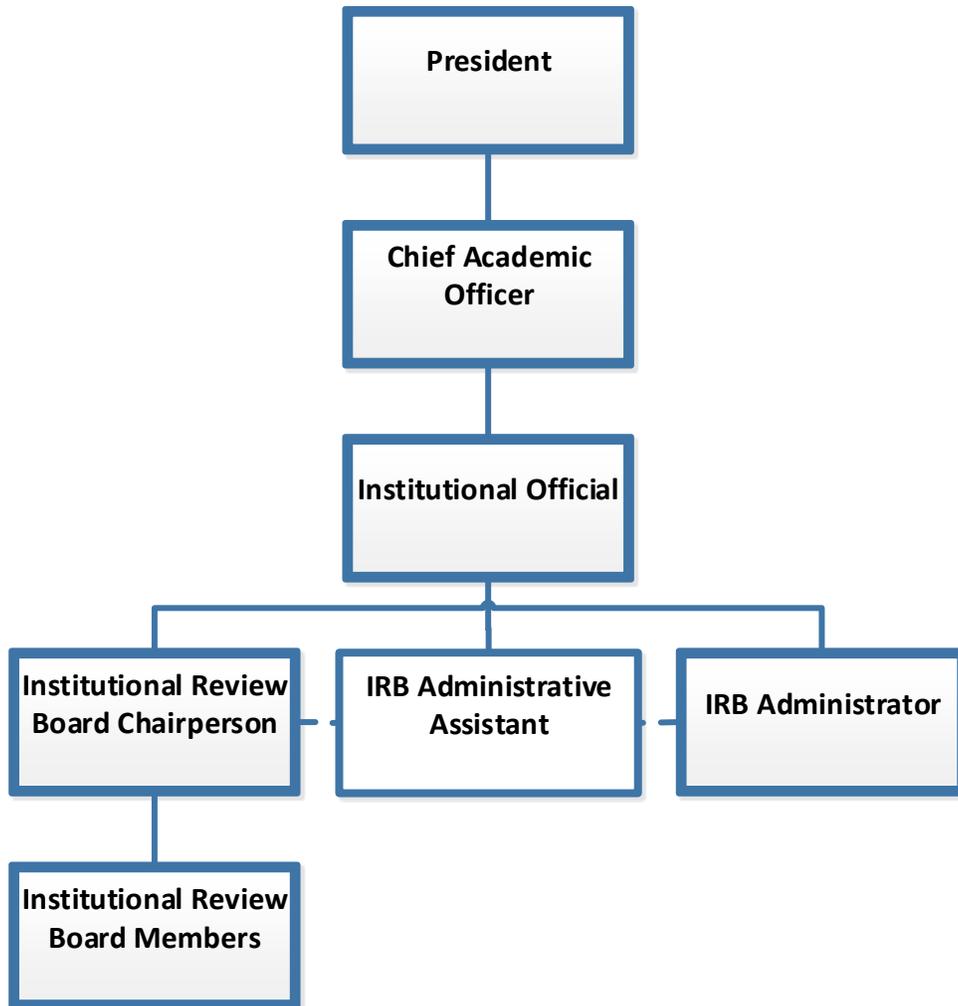
At Walsh University, the primary purpose of the IRB is to protect the welfare of human subjects used in research. Federal and state regulations mandate that research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) provided for in its assurance filed with the Office of Human Research Protections and will be subject to continuing review by the IRB. As an institution, Walsh University is committed to fostering the growth of human subjects' research by faculty and students for the greater good of humanity and for the pursuance of knowledge. Accordingly, the institution supports research that does not contradict or conflict with the language and intent of the mission of Walsh University.

### 1.4 Human Subject Research Oversight (organizational structure)

The IRB functions administratively through the Institutional Official and staffed within the Office of Academic Affairs. This structure provides for administrative coordination for the IRB with the

## Walsh University IRB Policy and Procedure Manual

various academic and administrative units in the university. The Chief Academic Officer through the authority of the President has direct supervisory line of the Institutional Official. The IRB through the Institutional Official and IRB Chair advises and makes recommendations to the Chief Academic Officer and/or President, to policy and administrative bodies, and to any member of the university community on all matters related to the use of human subjects in research. Revisions for policies and procedures are recommended by the IRB Chair and the Institutional Official and approved by the Chief Academic Officer. Figure 1 outlines the organizational structure of the IRB.



**Figure 1.** Organizational Structure of the Institutional Review Board.

The organizational structure of the IRB includes the Institutional Official who has administrative oversight through the authority of the President and Chief Academic Officer, an IRB Administrator, an Institutional Review Board Chairperson, and IRB Administrative Assistant. Institutional review board membership is made of volunteers from the community and university. The IRB at Walsh University will:

- i. consist of at least seven members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;

## Walsh University IRB Policy and Procedure Manual

- ii. make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
- iii. include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
- iv. include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
- v. not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- vi. have one member of the committee appointed as the Liaison for Undergraduate Research and have one member of the committee appointed as the Liaison for Graduate Research in addition to IRB duties.

### 1.5 Purpose and Scope of the Manual

This manual contains a current compilation of Walsh University rules, regulations, policies and procedures applicable to the protection of human research subjects, sets forth appropriate mechanisms for their implementation and is regularly updated to reflect new standards, regulations and the University policy (see section 1.4).

### 1.6 Applicability

The policies and procedures set forth in this manual are applicable to all faculty, staff, employees, and students at the University who propose to use human subjects in research, development, and related activities including research for which investigational devices or drugs are used. The IRB has jurisdiction and oversight responsibilities over human subject research in which the University is engaged. Specific examples would include but not be limited to research:

- The research is sponsored by this institution (unless the research is conducted at another institution), or
- The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another approved institution), or
- The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
- The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

Walsh University requires research principal investigators/researchers who are not its employees or agents:

- To obtain the collaboration of a University faculty member.
- To ensure all PIs/Researchers (internal and external to the institution) comply with all relevant a. IRB determinations, b. Federal and state regulatory requirements, and c. Human subject protection standards.

### 1.7 Revision and Maintenance of the Manual

The Office of Academic Affairs is responsible for maintaining and updating this manual. All new or revised manual materials will be placed on the Walsh IRB website by the Chair of the IRB or the IRB Administrator (see section 1.4)

# Walsh University IRB Policy and Procedure Manual

## Section 2: Definitions

### 2.1 Definitions Applicable to All Sections of this Manual

**Adverse events** are a subset of unanticipated problems involving risks to the subject or others and are related to untoward or unfavorable medically-related events, including any abnormal sign, symptom or disease temporarily associated with the subject's participation in the research or clinical trial.

**Agent of the Organization** is a faculty member or non-faculty employee, who may also be a Principal Investigator/Researcher of a research protocol or an Institutional Review Board member, or non-employees who perform institutionally designated activities or who exercise institutionally delegated authority or responsibility such as research or teaching activities. Examples would include community IRB members, University faculty who are conducting research at another institution, a faculty member performing research while on sabbatical or a University student conducting research at another institution as part of a course requirement.

**Allegation of Noncompliance** means an unproven assertion of noncompliance.

**Anonymity** means that the identity of a research subject cannot be readily ascertained by anyone, including the Principal Investigator/Researcher, either directly or through the use of coded data.

**Anonymous Data** pertains to information that is collected or that an individual has disclosed in a study with the expectation that the information has no identifiers linked to the participant and therefore cannot in any way be traced to the participant. An example would be survey research that does not ask for the participants' names or any other form of personal identification. The words "anonymous" and "confidential" do not have the same meaning and are not interchangeable.

**Applicable Clinical Trial** means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between the intervention and a health relationship. The definition includes surgical procedures, behavioral treatments, and Food and Drug Administration (FDA) regulated studies with drugs, biological products, or devices.

**Approved** means a protocol is approved as written with no explicit conditions.

**Approved Assurance** means a document that fulfills the requirements of 45 CFR Part 46 and is approved by the Secretary of Department of Health and Human Services (HHS).

**Approved with Explicit Conditions** means the protocol is approved with explicit conditions for minor changes or simple concurrence of the Principal Investigator/Researcher that will be identified to the Principal Investigator/Researcher and must be completed and documented prior to beginning the research. In most instances, the Institutional Review Board (IRB) Chair will review and approve but explicit conditions deemed as significant or are directly relevant to regulatory criteria must go back to the convened IRB for review and approval.

**Assent** means an affirmative agreement to participate in research or clinical investigation. Mere failure to object an absence of affirmative agreement may not be construed as assent. This most often is applicable to children and cognitively impaired adults.

## Walsh University IRB Policy and Procedure Manual

**Authorized deception** means that a Principal Investigator/Researcher has intentionally not described certain aspects of a research study but subjects are informed that certain information will be withheld until the subject completes the study tasks.

**Chairperson of the IRB** see Institutional Review Board (IRB) Chair.

**Children** are persons who have not attained the legal age for consent to treatments or procedures involved in research or clinical investigations. In Walsh University, where federal regulations and state law both apply, individuals under the age of 18 are considered to meet the definition of children. For research conducted outside Walsh University, children are defined under the applicable law of the jurisdiction in which the research or clinical investigations will occur. Some funding agencies may define children differently.

**Close community partnership research** is an ongoing collaborative project in which goals are co-defined in ways that balance benefit to the Principal Investigator/Researcher and utility of the findings for the community. There is some sharing of decision making between the Principal Investigator/Researcher and the community, but the research methodology is primarily determined by the Principal Investigator/Researcher. **Coded Information/Data** means that identifying information that would enable the Principal Investigator/Researcher to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

**Coercion** is an overt or implicit threat of harm that is intentionally presented by one person to another in order to obtain compliance. For example, a principal investigator/researcher might tell a prospective subject that his or her grades might suffer if they do not participate in the research.

**Collaborator** is anyone who plays a part in the protocol and has access to study records.

**Common rule** refers to Department of Health & Human Services 45 CFR Part 46, Subpart A.

**Community** is a group that self-identifies by geography, age, ethnicity, gender, sexual orientation, disability, illness or health condition, common interest or cause, a sense of identification or shared emotional connection, shared values or norms, mutual influence, or commitment to meeting a shared need. Community need not be defined solely by geography. Defining “community” in a community-university partnership is more about the process of asking questions than about a strict definition of who “is” community or “represents” community: “Are those most affected by the problem at the table? Are community members at the table? Are those who have a stake in the issue being addressed at the table? Do they play decision making roles?” The purpose of the research partnership drives the definition - each project must define the community of interest.

**Community-based participatory research (CBPR)** is a project defined by co-creation of project ideas and procedures by Principal Investigator/Researcher and a community, active and substantive participation by the community in all or nearly all stages of the research, and shared power and decision-making responsibilities. There is an expectation that findings will be used to change systems or solve community problems. CBPR sees research subjects as both

## Walsh University IRB Policy and Procedure Manual

individuals and as a community comprised of individuals. Issues of confidentiality in CBPR should be viewed differently than with individual subjects and decisions made as to what may or may not be appropriate.

**Community-based research** is research that takes place in or involves a community. The more precise definitions below reflect the degree of engagement of the community in the research, which can take place along a spectrum of engagement and shared governance.

**Community-placed research** is a researcher-initiated project involving a one time or short-term relationship between the Principal Investigator/Researcher and the community, with limited community involvement beyond being a venue for recruiting research subjects or for implementing research procedures.

**Confidential** pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission or in ways that are inconsistent with the understanding of the original disclosure. For example, there may be a legal responsibility to divulge information and that should be stated in the consent form. The words "anonymous" and "confidential" do not have the same meaning and are not interchangeable.

**Conflict of Interest** is defined as any situation in which financial or personal obligations may compromise or present the appearance of compromising an individual or group's professional judgment in conducting, reviewing, or reporting research. Members of the Institutional Review Board may not review, deliberate on or approve research if they have a conflict of interest related to the research. The conflict of interest includes that of the individual and their immediate family members defined as spouse and dependent children and step-children.

**Data and Safety Monitoring Plan (DSMP)** is an individualized plan, written by the Principal Investigator/Researcher responsible for the study. The DSMP sets forth mechanisms for reviewing and evaluating unanticipated problems and other study-relevant data. The rationale for requiring a DSMP is the need to enhance research subject safety by clearly defining safety related issues prior to subjects being enrolled in a study. These issues include:

1. Monitoring the safety of the environment including the safe handling of drugs, solutions, specimens, physical space, and equipment;
2. Monitoring and protecting the validity and integrity of the data collected for the study; and
3. Documenting, grading, attributing, and reporting unanticipated problems involving risks to subjects or others.

**De-Identified** refers to information or data where direct identifiers such as name and address have been removed. In common use, the term refers to data where it may still be possible to identify individuals by inference or through codes held by the principal investigator/researcher or a third party. Therefore data that is de-identified may not be anonymous because it may still permit at least probabilistic re-identification when analyzed in conjunction with other datasets.

**Deception** (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.

**Designated Reviewers** are experienced IRB members, defined in this policy as having been an IRB member for at least one year and having been trained on the expedited process by an IRB

## Walsh University IRB Policy and Procedure Manual

Chair. The IRB Chair has designated the IRB Vice Chair and other IRB members as reviewers of protocols requesting and qualifying for expedited review.

**Disapproved** means the protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas. The protocol and/or other documents will need to be completely re-written and re-submitted as a new submission. Principal Investigators/Researchers may request reconsideration of a determination for disapproval in writing and possibly be invited to attend an Institutional Review Board meeting and presenting reasons for reconsideration.

**Engaged in human subject research** as defined by the Department of Health and Human Services guidance document states that in general an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents, for the purposes of the research project, obtain:

1. Data about the subjects of the research through intervention or interaction with them.
2. Identifiable private information about the subjects of the research.
3. Informed consent of human subjects for the research.

**Enrollment** includes all subjects intended to be included in a study, including screen failures and drop outs. (Example: The principal investigator/researcher has a target enrollment of 100 and expects 75 to be screen failures so the study will accrue 25).

**Food and Drug Administration (FDA)** is an agency within the U.S. Department of Health and Human Services. FDA is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation.

**Financial Interest** in or related to the research means financial interest of any amount in the sponsor, product or service being provided, or a competitor of the sponsor. This can also be referred to as Financial Conflict of Interest.

**Guardian** means a person appointed by a court to have full authority to make decisions for and act on behalf of a child or cognitively impaired adult, except as otherwise provided for by law. For research conducted outside Walsh University, children are defined under the applicable law of the jurisdiction in which the research or clinical investigations will occur.

**HIPAA** is the acronym for the Health Insurance Portability and Accountability Act of 1996 and intended to provide standards for protecting the privacy of personally identifiable health information (PHI).

**Human Subject** has two definitions depending on the federal agency overseeing the research.

1. Department of Health and Human Services regulations define human subject as a living individual\* about whom the Principal Investigator/Researcher conducting research obtains:
  - a. Data through intervention or interaction with the individual; or
  - b. Identifiable private information
    - i. Intervention means both physical procedures by which data are gathered and manipulation of the subject or the subject's environment for research purposes.

## Walsh University IRB Policy and Procedure Manual

- ii. Interaction includes communications or interpersonal contact between the principal investigator/researcher and the subject, i.e., obtaining informed consent.
- iii. Private information includes information about behavior when the subject can reasonably expect that no observation is taking place and information that has been provided for specific purposes and which the subject can reasonably expect will not be made public (e.g., medical record). Private information is individually identifiable, i.e., the identity of the subject may be readily ascertained by the principal investigator/researcher. The definition provided in the [Common Rule](#) is expanded to include principal investigators/researchers, technicians, and others assisting principal investigators/researchers, when they serve in a "subject" role by being observed, manipulated, or sampled. For the purposes of this manual, research involving human biological specimens (e.g., urine, blood, tissue, and other bodily fluids) will be considered human subject research.

\*Note: Research on autopsy materials or specimens from deceased individuals is not considered to be human subject research. However, some research, such as genetic studies providing private medical information about living relatives may need IRB review.

2. Food and Drug Administration definition is an individual who is or becomes a participant in research, either as a recipient of a test article (investigational drug, biologic or device) or as a control and may be either a healthy human or a patient. The definition also includes an individual on whose specimen a device is used.

**Human Subject Research** has reference to two definitions defined by federal agencies.

1. Department of Health and Human Services defines human subject research as systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)) and includes a living individual about whom the principal investigator/researcher conducting research obtains:
  - a. Data through intervention or interaction with the individual.
  - b. Identifiable private information.
  - c. Data about the subjects of the research through intervention or interaction with them.
  - d. Identifiable private information about the subjects of the research.
  - e. Informed consent of human subjects for the research.
2. Food and Drug Administration (FDA) defines human subject research as (21 CFR 56.102):
  - a. A clinical investigation on one or more individuals who are or become participants in the investigation, either as recipients of a test article (drug, biologic, or device) or as controls and may be either patients or healthy non-patients.
  - b. The data obtained from participants (and controls) will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product, or data obtained from the use of a device (in vitro diagnostic device) on tissue specimens will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.

If the research does not meet either HHS or FDA definitions, it is not human subject research.

## Walsh University IRB Policy and Procedure Manual

**Incidents of Noncompliance/ Protocol Violations** means that Principal Investigators/Researchers did not adhere to Federal Regulations and/or The University of Walsh University policies, procedures, requirements, or Institutional Review Board determinations for conducting research involving human subjects.

**Incomplete disclosure** means that the Principal Investigator/Researcher withholds some information about the real purpose of the study or the nature of the research procedures.

**Individually Identifiable Information** means any information about a living individual that is linked, associated with, or contains the name or any details of the individual that would allow someone to be able to directly or indirectly identify a subject from the information collected.

**Informed Consent** means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Information conveyed in the informed consent procedure must include all essential elements listed later in this manual.

**Institution** means any public or private institution or agency (including federal, state, and local government agencies).

**Institutional Official (IO)** is the University official responsible for ensuring that the human research protection program has the resources and support necessary to comply with all federal regulations and guidelines that govern human subject research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance. At Walsh University, the President with recommendation from the Chief Academic Officer appoints the IO.

**Institutional Review Board (IRB) Administrative Assistant** will verify that CITI trainings are complete; logs IRB protocols; records IRB meeting minutes; maintains the IRB files; and answers the IRB telephone line and fields questions.

**Institutional Review Board (IRB) Administrator** will check IRB protocols for completeness; conducts exempt reviews; and facilitates reporting, trainings, and quality improvement.

**Institutional Review Board (IRB) Chair** is a faculty member who is appointed by the Institutional Official, through the authority of the President and Chief Academic Officer, to conduct the business of the IRB and serve as the public spokesperson for the IRB. The Chair organizes and facilitates full IRB meetings, directing discussions, leads review and voting on research proposals; assists with the establishment of IRB policies and procedures; assigns sub-committees of the IRB, if applicable; evaluates research proposals; identifies issues needing discussion and decision making; votes as a member of the IRB; delegates exempt reviews; conducts expedited reviews with a subset of the full IRB; monitors and reports any attempts to influence or coerce IRB members; resolves any issues arising during the work of the board or refer unresolved issues to the institution; and assists with reporting, trainings and quality improvement.

**Institutional Review Board (IRB) Member** will conduct expedited and full board reviews; assist students with protocols (liaisons), maintain up-to-date knowledge of regulations; ensure the rights, safety and welfare of human subjects.

## Walsh University IRB Policy and Procedure Manual

**Investigator/Researcher** is considered to be an individual performing various tasks related to the conduct of human subject research activities such as:

1. Obtaining information about living individuals by intervening or interacting with them for research purposes.
2. Obtaining identifiable private information about living individuals for research purposes.
3. Obtaining voluntary informed consent of individuals to be subjects in research.
4. Studying, interpreting or analyzing identifiable private information or data for research purposes.

**Lapse of approval** means that, for whatever reason, the Institutional Review Board (IRB) has not received or reviewed required documentation for protocol continuation prior to the protocol's expiration date and all research activities must cease. Continuing review of research activities by the IRB must occur at least annually and a request for continuation must be accompanied by a report and other pertinent documentation. By regulation, no grace period is allowed. The IRB notifies Principal Investigators/Researchers of lapses in approval and the requirement to cease all research activities until approval for continuation is obtained (currently with a "Cessation" letter).

**Legally authorized representative (LAR)** means an individual, judicial or other entity authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular research activity or procedure. For research conducted in Walsh University where federal regulation and Walsh University law both apply, for healthcare related treatments and procedures and for non-healthcare procedures, individuals in the following order may serve as a LAR: a legal guardian, persons appointed as health care agents under Durable Power of Attorney for Health Care, a spouse, adult child, parent, or an adult sibling. For research conducted outside of Walsh University, individuals who meet the definition of an LAR are those who are described under the applicable law of the jurisdiction in which the research will be conducted. Legal counsel may be consulted by the Institutional Official and the Institutional Review Board Chair for assistance in applying laws to research involving human subjects.

**Legally effective informed consent** means that the Principal Investigator/Researcher obtained consent to participate from a subject or the subject's legally authorized representative (LAR) and documented it in a manner consistent with the human subject protection regulations and applicable laws of the jurisdiction in which the research is conducted. It is expected that the Principal Investigator/Researcher will seek consent only under circumstances that provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate and to minimize the possibility of coercion or undue influence. The information provided in the consent process should be understandable to the subject or subject's LAR and may not include any exculpatory language.

**Liaison for Graduate Research** is a faculty member who is an IRB member, appointed by the IRB chair to assist faculty and graduate students with the development of graduate student research protocols and IRB applications.

**Liaison for Undergraduate Research** is a faculty member who is an IRB member, appointed by the IRB chair to assist faculty and undergraduate students with the development of undergraduate student research protocols and IRB applications.

## Walsh University IRB Policy and Procedure Manual

**Minimal Risk** means that the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. These are risks that reflect background risks that are familiar and part of the routine experience of life for an average person in the general population. For children, the definition means research in which 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 (of a healthy child) or during the performance of routine physical or psychological examinations or tests. For Prisoners, minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons who are not prisoners.

**Noncompliance** means that researchers or individuals other than researchers, such as research staff, Institutional Review Board (IRB) staff, or IRB members, did not adhere to Federal Regulations and/or Walsh University policies, procedures, requirements, or IRB determinations for conducting research involving human subjects.

**Office for Human Research Protections** is an office in the Office of the Secretary of Health and Human Services that is responsible for regulatory oversight of human subject research.

**Parent** means a child's biological or adoptive parent.

**Permission** means the agreement of parent(s) or guardian to the participation of the child in the research or clinical investigation.

**PHI** is the acronym for personal health information which is protected under the HIPAA regulations.

**Pregnancy** encompasses the period of time from implantation until delivery. A woman shall be assumed pregnant if she exhibits any of the presumptive signs of pregnancy, particularly missed menses, until the results of pregnancy testing are negative or until delivery.

**Principal Investigator/Researcher** means an individual under whose immediate direction research is conducted or in the event of research conducted by a team of individuals, is the responsible leader of that team. When Walsh University accepts a grant or contract from an outside sponsoring agency, certain legal and ethical obligations are stated or implied in the document of agreement. The University becomes responsible for the proper performance of the stated work and for fiscal management of the funds received from the sponsor. Sponsors usually require an individual be named to oversee the project with the reasonable assurance that the agreed responsibilities will be discharged faithfully and prudently in the mutual interest of the sponsor and the University and over the full period of the award.

In order to implement these obligations, only individuals in the categories shown below are authorized to be Principal Investigators/Researchers or project directors for sponsored projects. Only in rare instances will others be authorized, and then only with the written approval of the Institutional Official.

1. Members of the faculty in the professorial ranks (assistant professor, associate professor and professor)
2. Directors (code 1000)
3. Research scientists/engineers (code 1000) and senior research scientists/engineers (code 1000)

## Walsh University IRB Policy and Procedure Manual

4. Special research associates at the Applied Research Laboratory.
5. Students who list a full-time faculty member as a sponsor/mentor (or a part-time or adjunct faculty member when specifically requested by the department chair).
6. Adjunct faculty when Principal Investigator/Researcher status is specifically requested

**Prisoner** means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Some common examples of the definition are:

1. Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration.
2. Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to criminal prosecution or incarceration.
3. Individuals who have been voluntarily admitted for treatment or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others are not prisoners.
4. Parolees who are detained in a treatment center as a condition of parole. Parolees living in the community, even with community-supervised monitoring, are not prisoners.
5. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners. However, some situations of this kind may require analysis of circumstances and Office for Human Research Protections should be consulted when questions arise about research involving this population.

**Prisoner Advocate** is an individual representing the interests of incarcerated persons who may be approached and enrolled as research subjects.

**Privacy** means having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally or intellectually) with others.

**Privacy Board** is a review body that may be established to act upon requests for waiver or alteration of the requirement for a signed "Authorization for Use or Disclosure of Protected Health Information (PHI)" under the HIPAA Privacy Rule for uses and disclosures of PHI for a particular research study. A Privacy Board may waive or alter all or part of the Authorization requirements for a specified research project or protocol. The IRB may act as a privacy board.

**Private Information** consists of the following:

1. Information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical record).
2. Information that can be readily identified with individuals, even if the information was not specifically collected for the study in question.
3. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

**Protocol Deviation** means a deviation from Institutional Review Board-approved activities related to a research study. This means that the Principal Investigator(s)/Researcher(s) has performed activities that are different than those described in the protocol, that procedures not

## Walsh University IRB Policy and Procedure Manual

previously described in the protocol were performed, or that procedures described in the protocol were not performed.

**Quality Improvement (QI)** projects are defined as those activities that are designed purely to evaluate and improve practice or to improve clinical care to better conform to established or accepted standards or are designed to bring clinical care in line with evidence or consensus-based standards. These types of activities are generally not subject to Institutional Review Board (IRB) review and approval. However, if data from the QI activity are used to draw general or widely applicable conclusions beyond evaluating a particular program or activity, the activity probably is research. The distinction is not always clear. The intent to publish, in and of itself, does not require that an activity be reviewed by the IRB. If the activities and data being reported are a result of QI assessment, then no IRB review is required for the activity or for its publication.

**Quorum** is defined as a majority of the voting members. In the case of the Institutional Review Board (IRB), a quorum will consist of at least 51% of the voting IRB members and must include at least one non-scientific member. All members present have equal voting power. At meetings of the IRB, a quorum must be established and maintained throughout the entire meeting. A member with a conflict of interest cannot contribute to a quorum. For Food and Drug Administration-regulated research, a licensed physician must be present during the review, deliberation and voting to satisfy the quorum requirement under Code of Federal Regulations Title 21 CFR 56.108(c).

**Research** by definition of Department of Health and Human Services means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)) or, under Food and Drug Administration (FDA) regulations, an activity that involves a drug or drug, other than use of a market drug in the course of medical practice, or the use of a device to evaluate safety and effectiveness of that device, and data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product. If the activity is designed to improve internal practices it is not research (See Definition: Quality Improvement).

**Research Records** are records consisting of both Institutional Review Board-related records and any data gathered for research purposes.

**Research Safety and Compliance Officer** is a faculty member appointed by the Institutional Official with recommendation of the IRB Chair, who provides oversight, administration, implementation, and management of all IRB compliance business. The duties includes review of all protocol applications for research involving the participation of human subjects in research, ensuring that the university is in compliance with all federal, state, local regulations, policies and guidelines relating to research involving human subjects.

**Secretary** means the Secretary of Department of Health and Human Services (HHS) and/or any other officer or employee of the HHS to whom authority has been delegated.

**Sponsor** means any person or entity that takes responsibility for, initiates or funds a study. The sponsor may be an individual, pharmaceutical company, device manufacturer, governmental agency, academic institution, private organization, or other organization.

**Student** means any individual who is enrolled as a student at Walsh University.

## Walsh University IRB Policy and Procedure Manual

**Staff** means all employees of Walsh University.

**Suspension** means a temporary cessation of research activities, to include enrollment of new subjects, collection of data from enrolled subjects, and performance of any research activities described in the approved protocol. Suspensions can be administered by the Institutional Review Board (IRB), the IRB Chair, or the Principal Investigator/Researcher in order to eliminate an immediate hazard to subjects. A suspended protocol requires continuing review.

**Tabled** means generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications or conditions that, when met or addressed, require full Institutional Review Board (IRB) review and approval of the Principal Investigator's (PI)/Researcher's responses and revisions. The deficiencies will be specified to the PI/Researcher, and on occasion the PI/Researcher is asked to attend the full board meeting in order to clarify the points in question. The PI/Researcher must revise the protocol, consent forms, or other documents as specified by the IRB and re-submit.

**Termination** means a permanent discontinuance of research activities described in a research protocol due to withdrawal of Institutional Review Board (IRB) or regulatory agency approval. If subjects are currently enrolled, the IRB and Principal Investigator/Researcher must implement actions for immediate care of and safe withdrawal of subjects from the research study. A terminated protocol does not require submission for continuing review.

**Unanticipated problem involving risks to subjects and others** means any problem, event, occurrence or new information related to the research project that is unanticipated and indicates that subjects or others are at increased risk of harm.

**Undue influence** is an offer or implication, real or perceived, of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, professors recruiting their students may lead to the perception of undue influence to participate.

**Ward** is defined as a child who is placed in the legal custody of the state or other agency, institution or entity consistent with applicable federal, state or local law.

# Walsh University IRB Policy and Procedure Manual

## Section 3: General Policies and Procedures

### 3.1 Applicable Regulations and Laws

The purpose and responsibility of the Institutional Review Board (IRB) is to protect the rights and welfare of human research subjects. The IRB reviews and oversees research activities involving human subjects and requires that the research complies, as applicable, with Federal regulations at 45 CFR 46, Subparts A, B, C, and D, (or equivalent policies and procedures), the FDA 21 CFR Parts 50, 56, 312, and 812.

### 3.2 Institutional Review Board

#### 3.2.1 Purpose

Safeguarding the rights and welfare of subjects at risk in any research activity, whether financially supported or not, and irrespective of the source of any supporting funds, is primarily the responsibility of the institution. In order to provide for the adequate discharge of the institutional responsibility, no non-exempt research activity involving human subjects may be undertaken by any faculty, staff, employee or student at Walsh University unless an IRB has reviewed and approved the research prior to commencing the research activity.

#### 3.2.2 Designation and Authority

Walsh University has designated the IRB responsible for conducting initial and continuing reviews and providing oversight for all research activities involving the use of human subjects performed by agents or employees of Walsh University. The scope of research reviewed by the IRB is not limited and the IRB reviews all types of research submitted.

The President through the Chief Academic Officer and Institutional Official (IO) formally grants the IRB the following authority relative to the protection of human subjects:

1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the agents of the organization and involving human subjects, based on its consideration of the risks and potential benefits of the research and whether the rights and welfare of the subjects are adequately protected;
2. To require reports for protocol continuing review;
3. To continuously monitor the conduct of research with human subjects;
4. To suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious risk to subjects;
5. To place restrictions on a study, if necessary to protect human research subjects;
6. To observe, or have a third party observe, the consent process;
7. To observe, or have a third party observe, the conduct of the research.

No official within the organization may approve a protocol or human subject research activity that has not been approved by the IRB. However, the Institutional Official, Chief Academic Officer and/or President may disapprove a protocol or research activity that has been approved by the IRB if the protocol is contradictory to the mission of the university.

## Walsh University IRB Policy and Procedure Manual

### 3.2.3 Composition and Appointment of the IRB

The IRB personnel and structure is formally approved by the IO through the authority of the President and Chief Academic Officer of the University. The IRB committee is formally appointed by the IO, with input and membership nominations coming from the IRB Chair and IRB members, University department chairs, and self-nominations, and is composed of a sufficient number of members to assure complete and adequate review of activities commonly conducted at Walsh University. The composition of the IRB must meet the minimum regulatory requirements and the members must be sufficiently qualified through the maturity, experience, expertise, and diversity (experience, expertise, racial, cultural, and gender) to insure respect for their advice and counsel specific to safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the IRB is able to ascertain the acceptability of proposals in terms of organizational commitments, regulations, applicable law, standards of professional conduct and practice, and community attitudes and are constituted to meet those requirements.

The IRB at Walsh University will:

- i. consist of at least seven members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
- ii. make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
- iii. include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
- iv. include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
- v. not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- vi. have one member of the committee appointed as the Liaison for Undergraduate Research and have one member of the committee appointed as the Liaison for Graduate Research in addition to IRB duties.

Scientific members of the IRB generally will have had experience in research involving human subjects, and will be recruited from among active research members of the University. Nonscientific members will be recruited from the faculty as a whole and will reflect professional expertise in a non-scientific area, such as law, ethics, human or patient rights, etc. The appointment of non-affiliated (community) members and the IRB Chair is responsible for determining whether or not the nominees are truly unaffiliated and/or have appropriate expertise to serve as prisoner representative.

Up to three Alternate members may be appointed by the Institutional Official upon recommendation of the IRB Chair. Alternates are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The alternate

## Walsh University IRB Policy and Procedure Manual

member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research protocol and may be unable to make a fair and accurate determination of the risk-benefit ratio. For these protocols the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may call upon an ad hoc consultant for assistance in review for scientific merit or to perform an in-depth review of the study. The ad hoc consultants are not considered to be members of the IRB, are utilized only for expert scientific review, have no voting rights and must disclose whether or not he/she has any conflicts of interest with the protocol. The consultants will submit a written report and copies of the report will be distributed to all IRB members. The report and recommendations will be documented in the IRB minutes for the meeting. It is expected that, because of the wide diversity of IRB members, the use of ad hoc consultants will be a rare occurrence.

The IO may appoint administrative staff and/or faculty (e.g., legal counsel) at the University to serve as non-voting members of the IRB should the IO, the IRB Chair, or the IRB Administrator decide that such persons would be of assistance to the IRB in conducting its duties. A non-voting member cannot be counted in the quorum and cannot vote, but can participate in discussions and deliberations.

In addition, funding agencies may have additional IRB membership requirements. For example, the National Institute on Disability and Rehabilitation Research (NIDRR) specifies that when an IRB reviews an NIDRR-funded research project that purposefully includes children with disabilities as research subjects, the IRB must include at least one person whose primary interest is the welfare of children with disabilities. When reviewing these types of research projects, the IRB may use ad hoc reviewers with specific expertise in treating children with disabilities.

### 3.3 Term of Appointment

IRB members are appointed to a three-year term, which is consecutively renewable once. The IRB Chair and Vice Chair are expected to hold the positions for a minimum of 3 years. Upon appointment and again at time of annual reappointment, each IRB member is queried to determine roster information such as affiliation status, relationship of the member to the University, indications of experience and other relevant information. IRB member's performance will be reviewed annually by the IRB Chair and Vice Chair. IRB members who are not performing in accordance with the IRB's mission or policies and procedures or who have an undue number of absences will not be reappointed. Feedback will be provided to the members by the IRB Chair and IO.

### 3.4 Committee Officers

The IRB will have a Chair and a Vice Chair chosen from IRB members and will typically be members of the faculty of the University knowledgeable in human subject research, including the federal and state regulations, University policies, and ethics relevant to such research. The IRB Chair shall preside over and be authorized to speak for the IRB. Whenever the Chair is not available, the Vice Chair will assume the responsibilities of the IRB Chair during the period of their absence.

## Walsh University IRB Policy and Procedure Manual

### 3.5 Meetings

A meeting is when a quorum of members communicates in a designated forum. In order to conduct IRB business, there must be a quorum of members (3 of 5) at a convened meeting. If quorum is lost, votes are not taken until it is restored. To be approved, a protocol must receive a majority of votes of members. The IRB shall hold regular meetings at a time and place to be determined by the IRB and posted electronically. Principal Investigators/Researchers are welcome to attend to address specific concerns regarding research protocols but will be asked to leave the meeting during all deliberations and votes. Other members of the University community are permitted to attend meetings but, due to limited seating space, must request attendance through the IRB Chair. Guests may be asked to sign a confidentiality agreement.

Prior to each full board meeting the IRB Chair will review the agenda of protocols and will assign primary reviewer(s) knowledgeable about or experienced in working with these types of studies. The IRB Chair ensures that either the Primary or Secondary Reviewer is present at the meeting or available by teleconference during the convened meeting.

### 3.6 IRB Meeting Minutes

The IRB chair will monitor quorum at each meeting. Meeting minutes may be taken by an assigned administrative assistant. After all comments are reviewed and addressed if appropriate, a pending version of the minutes are available for review prior to and discussion at the next IRB meeting. A vote for approval of the final version of the minutes occurs at the next convened meeting. Once approved, the IO is notified and provided access to the secure location of the approved minutes in order to review all actions taken by the IRB.

*Minutes shall include:*

1. A protocol summary and the deliberations for each protocol and the resulting IRB action.
2. The approval period for each initial review, continuing review and amendment.
3. A record of attendance for each protocol including the names of members who left the meeting due to a conflict of interest and a notation of such.
4. The voting record for each protocol and the previous meeting's minutes reflecting the number of members for, against or abstaining from the vote and when alternate members replaced a primary member.
5. The basis for requiring changes to a protocol, tabling or disapproving research.
6. A written summary of the discussion and resolution of controverted issues.
7. Justification of deletions or substantive modifications of information concerning risks or alternative procedures contained in a HHS approved consent form.
8. If applicable, summaries of deliberations of protocols for inclusion of vulnerable populations.
9. If applicable, the rationale for significant risks/non-significant risk device determinations.
10. If applicable, protocol specific justifications for waivers of consent and research involving vulnerable populations.
11. A list of all actions that were taken administratively during the previous month.

# Walsh University IRB Policy and Procedure Manual

## 3.7 Confidentiality of the Review Process

During the process of initial, continuing review, or amendment of an activity, material provided to the IRB shall be considered privileged information and the IRB shall assure the confidentiality of the data contained therein.

## 3.8 Conflict of Interest

### 3.8.1 IRB Members – Convened Meeting

The IRB is charged with protecting research subjects from risks in research studies. Principles codified in the Nuremberg Code, the Declaration of Helsinki, Belmont Report, and existing federal regulations are employed to provide a framework for ethical considerations and assessment of risk and benefit in individual studies. The decisions made by the IRB are guided by these principles, but the IRB can only be successful if members are free of conflict of interest (COI).

Prior to discussion of protocols at a convened meeting, the IRB Chair will ask if any member has a COI with any protocol being discussed at that meeting. Should an IRB member declare involvement in any way in a research protocol under review by the IRB, or state a COI with the research protocol the following is required:

1. IRB member is excluded from discussion and voting except to provide information requested by the IRB.
2. IRB member leaves the meeting room during discussion and voting.
3. IRB member is not counted towards quorum.

### 3.8.2 Designated Reviewers for Expedited Review

IRB members who are IRB Chair designated reviewers for initial or continuing review of research protocols, reports of noncompliance, protocol deviations, unanticipated problems, and amendment requests that qualify for expedited review will self-identify any COI that they may have with the research or PI/Researcher. In such cases, the review responsibility will be reassigned to another experienced IRB member.

### 3.8.3 Examples of IRB Member COI

IRB members are considered to have a conflict of interest if they:

1. Are involved in the design, conduct, or reporting of the research study.
2. Have direct administrative powers over the investigators/researchers or the study.
3. Have a financial and/or ownership interest of any amount in or related to the research and the value can be readily determined.
4. Have a financial and/or ownership interest in or related to the research but the value cannot be readily determined.
5. Received or will receive compensation and/or have ownership interest of any amount with value that may be affected by the outcome of the study.
6. Have received in the past year, currently are receiving, or will receive from the sponsor of the study, honoraria, payments, or compensation of any amount.
7. Have a proprietary interest in the research, including but not limited to a patent, trademark, copyright, or licensing agreement.
8. Serve as directors, board members, scientific advisors or hold other decision making positions in the entity sponsoring the research.

## Walsh University IRB Policy and Procedure Manual

9. Are not a principal investigator/researcher, co-investigator/researcher, or consultant on a study, but are closely associated with the investigators/researchers on the study being reviewed, or other studies.
10. Have personal, familial, or intimate relationships with the Principal Investigator/Researcher.
11. For any reason, believe they cannot be objective concerning a study.

### 3.8.4 Principal Investigator (PI)/Researcher

All PIs/Researchers and their research staff are required to disclose any financial COI according to the University COI policy. Disclosed COIs that might affect the protection of subjects must have a management plan in place. Management plans may include: partial or complete divestment, limiting involvement of the conflicted individual, additional oversight, or disclosure. Disclosure alone cannot be used to manage conflicts of interests that might affect the protection of subjects.

When made aware of a possible PI/researcher conflict, the IRB formally refers cases to the IO, who in turn determines if formal COI management strategies are required. If required, the IO will request the PI/researcher prepare a draft COI Management Plan for submission for review. The IO will work with the PI/researcher to develop and finalize a COI Management Plan. When finalized, the COI Management Plan will be submitted to the IRB for review and final approval. Under no circumstances will research be approved until the IRB has reviewed and approved the COI Management Plan.

## 3.9 Training Requirements

### 3.9.1 Principal Investigators/Researchers

The University policy requires training for all faculty, faculty mentors, principal investigators/researchers, investigators/researchers and students, including researchers from other institutions who wish to conduct human subject research at the University. All key personnel (PI/Researcher, Co-PI/Researcher, Faculty Sponsor), originally listed or later added to a study through an amendment, must complete the required human subject training. In order to comply with the policy, investigators/researchers are required to complete the University's training affiliated with Collaborative Institutional Training Initiative (CITI). Completion of this training must be accomplished every three years. Webinars and local conferences are made available to the University community for additional training.

### 3.9.2 IRB Members

IRB members must complete the required human subject training.

## 3.10 Roles and Responsibilities

### 3.10.1 Principal Investigators/Researchers

The following are the PI/Researcher responsibilities and are not all inclusive:

1. Submit protocols for IRB review and approval of proposed research activities prior to commencing the research activities.

## Walsh University IRB Policy and Procedure Manual

2. Ensure that the research is conducted according to the protocol, any signed agreements, in compliance with all applicable laws and regulations and with the highest of ethical standards.
3. Submit for review and approval all proposed protocol and consent form changes prior to implementing the changes in the protocol except where necessary to eliminate apparent immediate hazards to human subjects.
4. Obtain legally effective informed consent from subjects prior to commencement of research activities, unless the requirement is waived by the IRB.
5. Ensure the rights, safety and welfare of the research subjects are upheld and protected.
6. Follow reporting requirements for problems that require prompt reporting.
7. Submit requested data at specified times for continuing review of ongoing research activities.
8. Upon completion of a study, honor all commitments that were agreed to as part of the approved research, e.g., providing information about the study results to research subjects or honoring commitments for reimbursements to subjects.
9. Upon completion of a study, submit a Closure Report to the IRB.
10. Disclose all conflicts of interest.
11. Retain records as required by the regulations, the sponsoring entity and local policy for the appropriate time period.
12. If you hold an IND/IDE, adhere to sponsor responsibilities in addition to principal investigator/researcher responsibilities as per 21 CFR Parts 312/812.
13. If appropriate, assure that applicable clinical trials (includes some of the NIH funded trials) are registered on the governmental database at <http://www.ClinicalTrials.gov>. Applicable clinical trials are defined by Federal Statute (Public Law 110-85). Generally, these trials include:
  - a. Trials of Drugs and Biologics: Controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation; and
  - b. Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.

### 3.10.2 Student Research Advisors

Mentorship to student research is a serious responsibility. It is time-consuming and requires an enthusiastic commitment to the students and to the program. In addition to tangible evidence of willingness to make a commitment to the students, mentors must have a demonstrated commitment to scholarship. In all likelihood, it may be the student's first experience with formal research. The success of the student's experience will be measured not only in the outcome of their projects, but also in what they learn from the faculty sponsor as a role model. These experiences will help form their perception of scientific research, and in some cases, determine whether a career in academic research is right for them. The following are the faculty mentor/sponsors responsibilities and are not all inclusive:

1. Advise the student on the selection of a topic, the content and preparation of their research proposal.
2. Assist student with the preparation of the IRB application. Complete and sign forms as required.
3. Serve as the IRB protocol Principal Investigator/Researcher of record for the student when the research meets the criteria for exemption from the regulations.
4. Obtain all necessary approvals (i.e., IRB) before initiating the project.
5. Ensure on-going compliance with federal regulations and institutional policies and procedures relating to human subject research.

## Walsh University IRB Policy and Procedure Manual

6. Guide and interact with the student throughout the research period. Remember, students should not be treated as if they were just another pair of hands to put to work. Teach them to think about their projects.
7. Assist the student to monitor and evaluate the progress of the study and appropriately report any unanticipated problems to you and the IRB.
8. Ensure that any continuing reviews are submitted in a timely manner.
9. Encourage students to present their results at other meetings or to co-publish them, if appropriate.
10. Advise and assist students with the preparation of poster presentations and papers, as applicable.
11. Be available to the student during the active research period.

### 3.10.3 Institutional Official

The IO is designated by the University President and has the authority to delegate activities as may be necessary to fulfill the following responsibilities:

1. Assure compliance with institutional policies and all applicable regulations for the protection of human research subjects.
2. Is legally authorized to represent the institution in matters regarding human subject research and is the signatory authority for all the Federal-Wide Assurance to the Office for Human Research Protections.
3. Responsible for review and evaluation of internal reports and QI activities.
4. Responsible for further institutional review and approval or disapproval of research approved by the University IRB (neither the IO nor any other University official can approve research that was disapproved by the IRB).
5. Reviews copies of all IRB meeting minutes, containing reports of IRB deliberations on human subject protocols, the results of QI audits, and noncompliance findings.
6. Signs all correspondence and reports sent to federal regulatory agencies regarding PI/Researcher or institutional noncompliance.

### 3.10.4 Institutional Review Board

IRB main responsibilities in safeguarding the rights and welfare of subjects are as follows and are not all inclusive:

1. Conduct review of initial protocol submissions, continuing reviews, and all revisions to protocols of human subject research conducted by the University principal investigators/researchers.
2. Approve, require modifications to secure approval, defer (table), or disapprove research activities overseen and conducted under the auspices of the University, regardless of location of the research activities.
3. Systematically analyze protocols for benefits to subjects and importance of knowledge to be expected and assess the potential benefits in relation to the potential risks involved in the research.
4. Report in writing the findings and actions of the IRB to the PIs/Researchers, IO, and, when applicable, to federal regulatory agencies or departments, as necessary.
5. Determine the interval at which ongoing studies need to be reviewed by the IRB (must be at least annually).
6. Determine which studies need verification from sources other than the principal investigator/researchers that no material changes have occurred since the previous IRB review.

## Walsh University IRB Policy and Procedure Manual

7. Observe, or have a third party observe, consent processes and/or the conduct of research.
8. Ensure prompt reporting of any changes in research activities to the IRB by principal investigators/researchers.
9. Ensure prompt reporting, by PIs/Researchers, to the IRB and/or federal agencies or departments (where applicable) of:
  - a. Unanticipated problems involving risks to subjects or others.
  - b. Serious or continuing noncompliance with regulations.
  - c. Suspension or termination of IRB approval.
10. Determine if studies involving drugs need an investigational new drug (IND) number designated by the FDA.
11. Determine if studies involving investigational devices pose significant or non-significant risk and whether an IDE is required.
12. Suspend or terminates approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.
13. If applicable, act as the Privacy Board for research involving use of PHI.

### 3.10.5 IRB Chair and Vice Chair

IRB Chair and Vice Chair responsibilities include:

1. Serve as public spokesperson for the IRB.
2. Chair convened meetings of the IRB.
3. Ensure adequate expertise for review and determinations.
4. Review protocols, continuing review reports, unanticipated problem and deviation reports, and other documentation submitted to the IRB.
5. Delegate review responsibilities as necessary and applicable.
6. Maintain up-to-date knowledge of human subject regulations and pertinent events.
7. Consult with investigators/researchers as necessary.
8. Suspend the conduct of research when individuals are placed at an unacceptable level of risk.
9. Collaborate with the IO and IRB Administrator to provide continuing education for IRB members.
10. Collaborate with the IO and IRB Administrator to resolve IRB-related issues with faculty or subjects.
11. Recognize and support partnership with IO to assure IRB efficiency and effectiveness.

### 3.10.6 IRB Members

IRB members' responsibilities include:

1. Be familiar with IRB policies and procedures and federal, state, and local regulations policies or guidelines relating to human subject research.
2. Review submitted proposals as assigned by the Chair or Chair's designee.
3. Review meeting packets in advance of IRB meetings and be prepared for discussion of submitted protocols.
4. Act as a primary or secondary reviewer of protocols when assigned.
5. Maintain confidentiality of IRB proceedings.
6. Disclose conflicts of interest, if applicable.

# Walsh University IRB Policy and Procedure Manual

## 3.10.7 IRB Administrator

IRB Administrator's responsibilities include:

1. Be familiar with IRB policies and procedures and federal, state, and local regulations policies or guidelines relating to human subject research.
2. Checks IRB protocols for completeness.
3. Reviews exempt protocols.
4. Facilitates reporting, trainings, and quality improvement.
5. Maintains confidentiality of IRB proceedings.
6. Discloses conflicts of interest, if applicable.

## 3.10.8 IRB Administrative Assistant

IRB Administrative Assistant's responsibilities include:

1. Verifies CITI training has been completed.
2. Logs IRB protocols.
3. Records meeting minutes.
4. Maintains IRB files.
5. Answers IRB telephone line and fields questions.
6. Maintains confidentiality of IRB proceedings.

# Walsh University IRB Policy and Procedure Manual

## Section 4: Initial IRB Review of Research Activities

### 4.1 Governing Principles/Regulations

The IRB will evaluate each proposed human subject research project on an individual basis to assess whether or not the principal investigator/researcher is adequately protecting the rights and well-being of the subjects. The governing principles for the IRB derive from those described and discussed in the Belmont Report. The governing regulations for the IRB are 45 CFR Part 46 and 21 CFR Parts 50, 56, 312, 600 and 812.

### 4.2 Exempt Research

The IRB recognizes the exempt categories described in Section 4.2.1. However, depending on the potential risks subjects may experience, the IRB may require a higher level of review either through the expedited process or by the IRB at a convened meeting.

Modifications that affect the exempt category or the criteria for exempt determination must be submitted as an amendment. Principal Investigators/researchers are strongly encouraged to contact the IRB Chair or an IRB member to describe any changes prior to submitting an amendment. The IRB Chair and/or member(s) can help principal investigators/researchers determine if a formal amendment is necessary or if the modification does not require a formal amendment process.

Formal continuing review will not be required, but principal investigators/researchers will be contacted at least every three years to determine if the research is still ongoing.

The exempt review proposal submission packet may be reviewed and approved by the IRB Administrator, IRB Chair, Vice Chair, or Other IRB Chair designated reviewer.

#### 4.2.1 Exempt Categories

The categories for exemption are as follows:

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

**Note:** For HHS funded research that involves children as subjects, the procedures cannot involve i) survey procedures; ii) interview procedures; or iii) observation of public behavior where the investigators/researchers participate in the activities being observed (observation of public behavior where the investigators/researchers do not participate is allowable).

## Walsh University IRB Policy and Procedure Manual

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above, if:
  - a. Human subjects are elected or appointed public officials or candidates for public office; or
  - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator/researcher in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

**Note:** This exemption would not apply if the investigator(s)/researcher(s) collects data in a coded manner since the code would enable subjects to be identified via the code. "Existing" means that the data, documents, records, or specimens must exist and be de-identified at the time the research proposal is submitted.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:
  - a. Public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service programs (e.g., social supportive or nutrition services as provided under the Older Americans Act);
  - b. Procedures for obtaining benefits or services under those programs;
  - c. Possible changes in or alternatives to those programs or procedures; or
  - d. Possible changes in methods or levels of payment for benefits or services under those programs.

In addition:

- e. The research must be conducted pursuant to specific federal statutory authority.
  - f. There must be no statutory requirement that an IRB review the research.
  - g. Research must not involve significant physical invasions or intrusions upon the privacy of the subjects.
  - h. The exemption should have authorization or concurrence by the funding agency.
6. Taste and food quality evaluation and consumer acceptance studies if:
    - a. Wholesome foods without additives are consumed.
    - b. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or
    - c. Agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## Walsh University IRB Policy and Procedure Manual

### 4.2.2 Criteria to Determine that Subjects of Exempt Research are Protected

Although exempt research is not covered by the federal regulations, it is not exempt from ethical considerations. The individual making the exempt determination will determine if additional protections are needed. The following are requirements for determinations of exemption:

1. The research involves no more than minimal risk to subjects;
2. Selection of subjects is equitable;
3. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data;
4. If there are interactions with subjects, there will be a consent process that will disclose such information as:
  - a. The activity involves research.
  - b. Description of the procedures.
  - c. Participation is voluntary.
  - d. PI's/Researcher's name and contact information.
5. There are adequate provisions to maintain the privacy interest of the subjects.
6. Subjects will be provided additional protections when appropriate.

### 4.2.3 Length of Approval Period

Since protocols that are exempt from IRB review are not approved by the IRB, there is no approval period. However, PIs/Researchers will be contacted every 3 years to verify that the research is ongoing and remains exempt. If the research is completed prior to the 3 year period, principal investigators/researchers are requested to notify the IRB of the study's closure.

### 4.2.4 Modifications to Exempt Research

Principal Investigators/Researchers should notify the IRB of proposed modifications to research determined to be exempt to assure that the research activities remain exempt for IRB review and exempt determination.

### 4.2.5 Notification of Determination: Exempt Research

If the research study is determined to meet the criteria for exempt status and if the PI/Researcher Assurance Statement has been received, the IRB Chair will send an Exempt Determination letter to the PI/Researcher. The exempt determination will be recognized for three years.

By agreeing to the PI/Researcher Assurance Statement, the principal investigator/researcher assures that all principal investigators/researchers and co-investigators/researchers are trained in the ethical principles, relevant Federal Regulations and institutional policies governing human subject research. The investigator/researcher assures that:

1. Human subjects will voluntarily consent to participate in the research when appropriate (e.g., surveys, interviews) and will provide subjects with pertinent information such as risks and benefits of participation, contact information for principal investigators/researchers and the IRB office, etc.
2. Human subjects will be selected equitably, so that the risks and benefits of the research are justly distributed.

## Walsh University IRB Policy and Procedure Manual

3. The IRB will be immediately informed of any information, unanticipated problems that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full Board Review.
4. The IRB will be immediately informed of any complaints from participants regarding their risks and benefits.
5. Confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects.

### 4.3 Expedited Review

If a protocol has been determined to be minimal risk it may be considered for expedited review provided that it fits one of the categories authorized by 45 CFR 46.110 for expedited review. Research including prisoners and involving direct interaction with the prisoners may be reviewed by the expedited review process if a determination is made that the research is minimal risk for the prison population being studied or included and a prisoner representative must review the research as either a primary or secondary reviewer. Research that does not involve interaction (e.g., existing data, record review) with prisoners may be reviewed by the expedited review process if a determination is made that the research is minimal risk for the prison population being studied or included. A prisoner representative may review the research but review by a prisoner representative is not required.

The expedited review proposal submission packet may be reviewed and approved by the IRB Chair, Vice Chair, or other IRB Chair designated reviewer.

#### 4.3.1 Submission and Review Schedule

Protocols submitted for expedited review may be submitted at any time and will be processed within the appropriate timeframe.

#### 4.3.2 Submission Requirements/Materials Reviewed

If the protocol meets all requirements for expedited review, the following must be electronically submitted:

1. A completed original IRB application with relevant electronic signatures (i.e., PI/researcher, co-investigator(s)/researcher(s), faculty advisor).
2. A research proposal describing the rationale for the study, research questions to be answered, methods, procedures, data analysis plan, and other required information. The research proposal must follow the outline in the Research Proposal Template.
3. An informed consent document.
4. Training verification.
5. Recruitment materials; i.e., flyers, posters, web-pages, email messages, etc.

If applicable:

6. Letters of support from external sites.
7. Sponsor protocol.
8. Copy of the grant application.
9. Cooperating institution's IRB approval

## Walsh University IRB Policy and Procedure Manual

### 4.3.3 Assignment of Expedited Reviewer

Upon processing, the IRB Chair, in consultation with IRB members if needed, will verify the protocol is appropriate for expedited review. They will work with the PI/Researcher to assure that all required documentation has been uploaded and the application is complete. The research protocols are then presented to the IRB Chair, Vice Chair, or designated reviewer.

### 4.3.4 Reviewer Considerations

Protocols undergoing expedited review are reviewed to assure:

1. The research meets all applicability criteria and falls into **one or more categories** of research eligible for review using the expedited procedure. 45 CFR 46.110
2. The regulatory criteria for approval are met.
3. Principal Investigators/Researchers and their research staff have appropriate and sufficient qualifications, expertise, and training.

### 4.3.5 Applicability Criteria

The following criteria should be considered for research undergoing expedited review:

1. The research procedures present no more than minimal risk to subjects.
2. The identification of subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
3. The research is not classified.

### 4.3.6 Criteria for IRB Approval of Research

In order to approve research, the IRB will provide ethical and scientific review of all human subject research to determine that all of the **requirements** of 45 CFR 46.111 criteria for IRB approval of research are satisfied.

Protocols that may be minimal risk but are not included on the list of activities that may undergo expedited review are reviewed at a convened meeting of the IRB. The IRB may then designate that a protocol is minimal risk and determine that the protocol may undergo an expedited review process during its subsequent reviews for continuation.

### 4.3.7 Scientific/Scholarly Review

The IRB relies on the integrity of the research team for scientific/scholarly applications. In these cases, the IRB review will include an evaluation of:

1. Whether the research uses procedures consistent with sound research design and which do not unnecessarily expose subjects to risk,
2. Whether the research is designed to answer the proposed question, and;
3. The importance of the knowledge reasonably expected to result from the research.

## Walsh University IRB Policy and Procedure Manual

### 4.3.8 Length of Approval Period

The interval for continuing review will be at least once per year (not to exceed 365 days; 366 days during a leap year) but may be shorter. If the protocol was approved or approved with explicit conditions, the expiration date is specified upon approval and dictated from the date of approval by the IRB Chair or designated reviewer. Research activities may not continue after midnight of the expiration date.

### 4.3.9 Reporting of Expedited Review to the IRB

The protocol number, title, PI/Researcher name, and the category of research for which each protocol that was approved using an expedited review procedure is reported to the IRB at the next scheduled meeting.

### 4.3.10 Notification of Determination: Expedited Review

Within 10 work days after the protocol is reviewed by a designated reviewer, the PI/Researcher will receive a letter of the IRB determination. An approval letter requires no further action and the PI/Researcher can begin research. Letters giving approval with explicit conditions will contain a list of required conditions and PIs/Researchers will not receive final approval until all conditions have been met. When the PI/Researcher has responded appropriately and completely in a letter to the IRB office addressing all conditions, then final approval is granted. The PI/Researcher will be notified by an approval letter that research can begin and when the protocol will require continuing review.

For tabled protocols, the PI/Researcher will be notified by letter of the reasons the protocol was tabled. In order to have the protocol reviewed again, the PI/Researcher must respond to all the tabled reasons by adjusting the submission documents or attaching additional supportive documentation.

Due to the high volume of protocols reviewed by the IRB, any protocol for which no PI/Researcher response to approved with explicit conditions or tabled is received in 60 days will be a withdrawn from IRB consideration. Reconsideration of the protocol will require complete re-submission.

## 4.4 Full IRB Review

Generally, protocols that must be reviewed at a convened meeting or otherwise are considered as more than minimal risk studies. The IRB will evaluate each project on an individual basis in order to assess whether the PI/Researcher is providing adequate protection for the subjects. The assessment will be based on the initial IRB application, which includes the applicable documents listed in Section 4.4.1.

### 4.4.1 Submission and Review Schedule

If the proposal meets all requirements for full board review, the following is required to be electronically submitted and included in the submission packet:

1. A completed original IRB application with relevant electronic signatures (i.e., PI/researcher, co-investigator(s)/researcher(s), faculty advisor).

## Walsh University IRB Policy and Procedure Manual

2. A research proposal describing the rationale for the study, research questions to be answered, methods, procedures, data analysis plan, and other required information.
3. An informed consent document.
4. Training Verification.
5. Recruitment materials; i.e., flyers, posters, web-pages, email messages, etc.
6. When necessary, a Data and Safety Monitoring Plan (DSMP)
7. Copies of all instruments if the study must be included (i.e., questionnaires, surveys, or outcomes measures).

If applicable:

8. Letters of support from external sites.
9. Sponsor protocol.
10. Copy of the grant application.
11. Cooperating institution's IRB approval

### 4.4.2 Data and Safety Monitoring Plans

Research studies in which subjects are at greater than minimal risk of experiencing physical or psychological injury (e.g., clinical/biomedical or behavioral studies that deliver an intervention to subjects) must consider how study data will be monitored and unanticipated problems addressed to assure the ongoing safety and well being of subjects during the study. In these types of studies, a Data and Safety Monitoring Plan (DSMP) that addresses the following must be submitted:

1. Type of data or events that are to be captured under the monitoring provisions. The monitoring provisions should be tailored to the expected risks of the research, the type of subject population being studied, the nature and size of the study, and the complexity of the research protocol.
2. Frequency of assessments of data or events captured by the monitoring provisions (e.g., at certain points in time or after enrollment of a certain number of subjects).
3. Entity or person(s) responsible for monitoring the data collected, including data related to protocol deviations, and unanticipated problems and their respective roles in the research activities (i.e., investigators/researchers, research coordinators, statisticians, independent medical monitor, etc.).
4. Procedures for analysis and interpretation of the data.
5. Time frames for reporting protocol deviations and unanticipated problems to the monitoring entity.
6. Definition of specific triggers or stopping rules that will dictate when action is required and what the range of possible actions is.
7. Reporting mechanisms/procedures for the data monitor and others responsible for communicating with the IRB, the study sponsor, the principal investigators/researchers and other appropriate officials the outcome of the reviews of the monitoring entity.

### 4.4.3 Assignment of Primary and Secondary Reviewers

Protocols undergoing initial and continuing Full IRB review are assigned to Primary and Secondary Reviewers by the IRB Chair. The reviewers are tasked with an initial review to assure appropriate review process, highlight any concerns for human subject protection, and to prepare for leading the presentation of the protocol to the full IRB.

## Walsh University IRB Policy and Procedure Manual

### 4.4.4 Distribution of Submitted Materials to IRB Members

The protocol information will be sent to the IRB members 10-12 days prior to the scheduled meeting. IRB members are expected to review at least the application, protocol and consent forms for research studies being considered at the meeting but, of course, may review all submitted materials as follows:

1. Application form.
2. Full protocol.
3. Informed consent document
4. Request to include vulnerable populations as subjects (pregnant women, children, prisoners, cognitively impaired adults).
5. Recruitment material.
6. Copies of all instruments if the study involves the use of questionnaires, surveys, or similar instruments.

If applicable:

7. Letters of support from external sites.
8. Sponsor protocol.
9. Copy of the grant application.
10. Cooperating institution's IRB approval

### 4.4.5 IRB Meeting Schedule

The IRB is generally scheduled to meet monthly but may be adjusted as necessary to accommodate member schedules, semester breaks, and other factors that affect member availability. The schedule may be viewed on the IRBs website.

### 4.4.6 Presentation and Discussion of Protocols

Protocols undergoing initial and continuing review at the convened meeting are presented individually to the IRB by the Primary and Secondary Reviewers. The IRB Chair, in consultation with members as needed, will assure members with appropriate scientific expertise, local knowledge and other expertise specific to the protocols are present at the IRB meeting, along with at least one member who is knowledgeable about or experienced in working with vulnerable subjects, when research involving subjects who are vulnerable to coercion are reviewed. If a member with the appropriate expertise, knowledge, or experience in working with the specific vulnerable population cannot be present, the IRB Chair will obtain a consultant, if needed, to provide a written report of their evaluation of the protocol. To be properly presented and discussed, a quorum of the members (which must include a non-scientist and a prisoner representative if research including prisoners is discussed) must be present for the entire presentation, discussion, and deliberation. Members not present for a substantial part of the discussion and deliberations should abstain from voting. The PI/Researcher of a proposal on the agenda may request to attend the meeting and may provide clarification upon request of an IRB member. For those protocols undergoing initial review, the following are discussed in detail (list is not all-inclusive):

1. The regulatory criteria for approval at 45 CFR 46.111 are met.
2. The setting in which the research occurs.
3. The scientific and ethical justification for including vulnerable populations (children, prisoners, pregnant women, cognitively impaired adults), if applicable.
4. Analysis of the procedures to minimize risk.

## Walsh University IRB Policy and Procedure Manual

5. The procedures to be used to ensure protection of subject privacy and data confidentiality.
6. The scientific qualifications and experience of the investigators/researchers and their research staff.
7. The human subject protection training of the investigators/researchers and their research staff.
8. Potential or disclosed investigator/researcher conflict of interest.

If applicable:

9. The scientific and ethical justification for excluding classes of persons from the research.
10. DSMP.
11. Written consultant reports. (If the protocol was reviewed by a consultant, the consultant will not be present for deliberation and the voting on the protocol.)

### 4.4.7 Criteria for IRB Approval of Research

In order to approve research, the IRB will provide ethical and scientific review of all human subject research to the extent necessary to determine that all of the requirements of 45 CFR 46.111 Criteria for IRB approval of research are satisfied. To ensure that all regulatory requirements for review have been met, a checklist is utilized. Additionally, an IRB Guide containing a list of the requirements and reminders for other required determinations is distributed to each member at the IRB meetings.

### 4.4.8 Scientific Review

At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research protocol and may be unable to make a fair and accurate determination of the risk-benefit ratio. For these protocols the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may call upon an ad hoc consultant for assistance in review for scientific merit or to perform an in-depth review of the study. The ad hoc consultants are not considered to be members of the IRB, are utilized only for expert scientific review, have no voting rights and must disclose whether or not he/she has any conflicts of interest with the protocol. The consultants will submit a written report and copies of the report will be distributed to all IRB members. The report and recommendations will be documented in the IRB minutes for the meeting. It is expected that, because of the wide diversity of IRB members, the use of ad hoc consultants will be a rare occurrence.

### 4.4.9 Length of Approval Period

The IRB will also determine the interval for the continuing review of the research, appropriate to the degree of risks that will be experienced by subjects. The interval for continuing review will be at least once per year (not to exceed 365 days; 366 days during a leap year) but may be shorter. If the protocol was approved or approved with explicit conditions, the expiration date is calculated from the date of the convened meeting. Protocols that have not undergone continuing review will expire at midnight on the expiration date. Research activities may not continue after midnight of the expiration date. The following conditions are likely to require review more often than annually:

1. There is a high degree of risk to subjects.
2. The stage of research is such that many of the risks are unknown.

## Walsh University IRB Policy and Procedure Manual

3. The proposed procedures have not been used in humans.
4. There have been confirmed instances of serious or continuing noncompliance.
5. An IRB member believes more frequent review is required.
6. Other reasons for which the IRB requests closer monitoring.

### 4.4.10 Notification of Determination: Full Board Review

Within 10 working days after each IRB meeting a letter is prepared and sent to the PI/Researcher of each protocol notifying them of the IRB determination for the protocol. An approval letter requires no further action and the PI/Researcher can begin research.

Letters giving approval with explicit conditions will contain a list of required conditions and PIs/Researcher(s) will not receive final approval until all required conditions have been met. Along with the determination, the IRB will determine whether the PI's/Researcher's responses to the explicit conditions will need to be reviewed for appropriateness and completeness at another IRB convened meeting or by the IRB Chair or designated reviewer. Responses to clarifications that are directly relevant to regulatory criteria must be reviewed by the convened IRB. When the PI/Researcher has responded to all conditions appropriately and completely in a letter to the IRB office then final approval is granted. The PI/Researcher will be notified by an approval letter that research can begin and when the protocol will require continuing review.

For tabled protocols, the PI/Researcher will be notified by letter the reasons the protocol was tabled. The entire submission packet, with all required documents, must be revised as needed and resubmitted. The PI/Researcher of protocols that are disapproved will receive a letter that delineates the reasons for disapproval.

## 4.5 Possible IRB Protocol Determinations

Either the IRB at a convened meeting or a designated reviewer (expedited protocols) will render one of the following determinations for each protocol:

1. **Approved:** Approved by the IRB as written with no explicit conditions.
2. **Approved with Explicit Conditions:** Approved with requirements for minor changes or simple concurrence of the PI/Researcher. These will be identified to the PI/Researcher and must be completed and documented prior to beginning the research. For these conditions, the IRB Chair, in consultation with the designated primary and secondary reviewers, upon reviewing the PI's/Researcher's response(s) to the conditions, may approve the research on behalf of the IRB. PI/Researcher responses to conditions deemed to be significant or that are directly relevant to regulatory criteria must be reviewed by the IRB at a convened meeting.
3. **Tabled:** Generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications, or conditions that, when met or addressed, require full IRB review and approval of the PI's/Researcher's responses and revisions. The deficiencies will be specified to the PI/Researcher, and on occasion the PI/Researcher is asked to attend the full board meeting in order to clarify the points in question. The PI/Researcher must revise the protocol, consent forms, or other documents as specified by the IRB and re-submit the entire protocol packet for full review at a convened meeting. The PI/Researcher may request reconsideration of determination by submitting a written response to the IRB.

## Walsh University IRB Policy and Procedure Manual

The IRB will invite the PI/Researcher to the IRB meeting if the IRB has additional questions. The IRB will reconsider its original decision in light of new information presented by the PI/Researcher. The second decision is final.

- 4. Disapproved:** This determination may only be made at a convened IRB meeting. The protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas. The protocol and/or other documents will need to be completely re-written and re-submitted as a new submission. PIs/Researchers may request reconsideration of disapproved studies by submitting a written response to the IRB. The IRB will invite the PI/Researcher to the IRB meeting if the IRB has additional questions. The IRB will reconsider its original decision in light of new information presented by the PI/Researcher.

For those protocols reviewed using the expedited review process, the designated reviewer may render decisions of approved, approved with explicit conditions, or tabled. The designated reviewer may not render a decision of disapproved. A decision of protocol disapproval may only be rendered by the IRB at a convened meeting.

Due to the high volume of protocols reviewed by the IRB, any protocol for which no PI/Researcher response to approved with explicit conditions or tabled is received in 60 days will be withdrawn from IRB consideration. Reconsideration of the protocol will require complete re-submission.

### 4.6 Final Approval and Expiration Dates

If a study is approved with no conditions, the final approval is effective the day the study is approved, i.e., the date of the convened IRB meeting for full board protocols and the date of reviewer's approval for expedited protocols.

If a study is approved with explicit conditions, the final approval is effective on the day the protocol was reviewed and conditions were imposed by the IRB at a convened meeting (full board protocols) or the date that the reviewer imposed conditions (expedited protocols). This determination will be documented in the IRB meeting minutes. The expiration date for the approval is based on the date it was approved at a convened meeting or approved by a designated reviewer and will be no longer than 365 days (366 days if during a leap year) from the approval date, but may be sooner if more frequent review is stipulated by the IRB.