Institutional Review Board (IRB) Policies and Procedures
I. **Statement of Principles and Purpose**

Persons conducting research involving human subjects have both an ethical and a professional obligation to ensure the safety, protection, and rights of participants. It is the intent of Armstrong State University through the Institutional Review Board (IRB) to assist those engaged in research involving human subjects to conduct their research along ethical guidelines that reflect professional as well as community standards. Armstrong recognizes its duty and obligation to protect the rights and welfare of human beings who are subjects in research regardless of the source of funding.

The IRB is a unique body within the university that has one purpose: the protection of human beings who are the subjects of research. This body must be knowledgeable about human subject research and have the experience necessary to evaluate research proposals. Its members are selected by the president of the university in consultation with the provost and vice president of academic affairs and the deans of the colleges. Records of this body reside in the Office for Academic Affairs.

The university has an obligation to ensure that all research involving human subjects meets regulations published in the United States Code of Federal Regulations (CFR), under Title 45, Part 46. It is not the intent of the university or the IRB to interfere in any manner with competent, ethical, and sound research involving human subjects. However, the university must ensure that its personnel act in compliance with federal, state, university system, as well as its own institutional regulations because the manner in which university researchers conduct research reflects upon our professional, personal, and community commitments to the ethical and scientific standards of conduct.

It is likely that all possible contingencies may not have been foreseen nor considered in the development of these guidelines and procedures. The IRB requires the cooperation of the university’s research community in establishing the means to assure adequate protection of human subjects involved in research. Therefore, the IRB invites input from investigators and other interested parties regarding the revisions and updates to these guidelines and procedures.

IRB approval means that the IRB has determined that the potential risks to human subjects are, in its collective opinion, acceptable. Further, it means that the research may be conducted at the institution within the constraints set forth by federal and institutional requirements. According to 45 CFR 46.109, an IRB has the authority to approve, require modifications in research to allow approval, or disapprove all research activities covered under this Federal policy. Research approved by the IRB may be subject to additional review
for approval or disapproval by officials within the institution; however, those officials may not approve research that has not been approved by the IRB.

II. Definitions
The United States Code of Federal Regulations provides the following definitions:

Research means the “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Other criteria that may be used to determine whether a planned activity is research include:
- The collection of data with the intent to report it in scientific publications;
- Use of a standard procedure or medication if it is influenced by any consideration other than direct welfare to the patient, even if both therapies seem equal to the physician in charge;
- Use of experimental drugs or devices.

Student research, as part of a class, would not require IRB approval if it meets all of the following criteria:
- It is a project which is a normal part of a student’s coursework;
- It is supervised by a faculty member;
- It has as its primary purpose the development of the student’s research skills;
- It does not present more than minimal risk to the participant or to the student investigator; and
- It is not genuine research that is expected to result in publication or some other form of public dissemination.

However, any student research project not meeting the criteria presented above must follow IRB procedures. It is recommended that researchers submit IRB applications to the IRB chair for review of exempt status.

Graduate students completing a thesis, practicum, dissertation, or project requirement involving human subjects must submit an application to the IRB. In addition, the student must append to the IRB application a copy of his/her certificate demonstrating completion of training in the protection of human research subjects. The approval notification from the IRB must be included in the appendix of each thesis, practicum, dissertation, or required project.
III. IRB membership

Membership will be consistent with the CFR, Title 45, Part 46, Section 46.107. Members will be appointed for terms of three years by the provost in consultation with the deans of colleges. Attention must be paid to the diversity of the membership, including race, gender, and cultural backgrounds. Membership will consist of a minimum of nine individuals, including one faculty representative from each College. One IRB member will not be otherwise affiliated with Armstrong. There will be two members from areas not normally associated with research involving human subjects. At least two members will be primarily involved in the scientific arena. At least one assistant dean and one department head will be selected to serve. Members must be sufficiently qualified through experience and expertise to serve. Armstrong faculty who serve on the IRB must be full-time faculty (including instructors, lecturers, and senior lecturers with 6 or more years of service to Armstrong). The majority of faculty members must be tenured. Multiple members from the same department are not allowed. Each member, including the chair, will provide documentation of approved training in the protection of human research subjects as a condition of service.

A list of the IRB members, identified by name, professional title/rank, and representative capacity, will be published annually. The list will be kept current by the chair of the IRB or his/her designee.

The IRB may invite individuals with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that of the IRB members. However, these individuals may not vote with the IRB.

The IRB Chair and Vice-Chair

The chair of the Armstrong IRB will be appointed by the provost. The chair must hold the doctoral degree, be a tenured member of the Armstrong faculty, and possess the professional competence necessary to review research activities, ascertain their acceptability in view of institutional commitments and regulations and applicable law as well as standards of professional conduct and practice.

The IRB vice-chair will be an Armstrong faculty member who holds the doctoral degree and is tenured. This individual will have all associated responsibilities and obligations of the chair when the chair is unable to serve in that capacity or when the chair is an investigator on a research project being considered or reviewed by the IRB. The duties and responsibilities of the vice-chair are the same as for any IRB member except when assuming the authorized role of the
chair. The vice-chair will serve for one year and may be considered for reelection at the end of each term of office.

Election of the vice-chair shall occur at the first regularly scheduled meeting of an academic year. Nominations will come from the floor and self nomination is permissible. A quorum of two-thirds majority must be present to conduct the election.

**Removal of an IRB Member before Expiration of an Appointed Term**

Should any IRB member, including the chair, conduct himself/herself in a manner that disrupts the work of the IRB or calls into question his/her ethical or professional competence, that member may be removed from the IRB by a majority vote of the membership. The membership will petition the provost to appoint a new member.

**IV. Administrative Duties**

The chair of the IRB shall be responsible for registering with Office of Human Research Protections (IRB00002899) and the US Department of Health and Human Services a Federalwide Assurance (FWA) for the Protection of Human Subjects (FWA00003981).

Research protocols involving human subjects will be presented to the chair of the IRB for evaluation and categorization. The Chair will determine whether a protocol falls into the EXEMPT, EXPEDITED REVIEW, or FULL REVIEW category according to the procedures outlined in this document.

The chair of the IRB is authorized to review any project submitted for IRB review that has been reviewed previously by a federal agency or by another university’s IRB. Such review will ascertain whether the previous review has met Armstrong’s IRB standards. The chair may determine whether the project is to be expedited or is to receive a full review. IRB applications from external applicants must contain a letter of support to conduct the study with Armstrong faculty, staff or students from the appropriate vice-president or president of Armstrong State University pending IRB approval.

The primary function of the IRB is to review and evaluate research proposals that fall into the EXPEDITED REVIEW or FULL REVIEW categories. Duties of the IRB’s chair require the review of all submitted research proposals as well as additional duties described in this document.

**V. Initial Categorization and Review of Protocols**
The chair of the IRB will review all submitted protocols to determine which of the following three categories is applicable for each:

A. **EXEMPT.** The chair reviews the protocol and notifies the investigator within seven (7) working days of protocol admission.

B. **EXPEDITED REVIEW.** The protocol is reviewed by the chair or vice-chair and at least one other member of the IRB. The chair may ask additional members to participate in an expedited review where such participation is deemed appropriate. The designated reviewers must vote unanimously for approval of an expedited review protocol. If there is no unanimous vote for approval, the protocol is automatically considered by the full IRB at its next scheduled meeting. A protocol cannot be disapproved through the expedited review process. Investigators will be notified of the findings of an expedited review within fifteen (15) working days of the protocol submission.

C. **FULL REVIEW.** The protocol is reviewed by the full board at its next regularly scheduled meeting, and the chair notifies the investigator(s) in writing within seven (7) working days of the findings and actions regarding their protocol. All protocols must be submitted at least twenty (20) working days before the scheduled IRB meeting. It is the policy of Armstrong’s IRB that protocols with the following procedures shall go before a full review:
   a. Ingesting, injecting, or absorbing any substances into the body.
   b. High expenditures of physical effort that could lead to physical injury
   c. Inserting any objects into bodies through orifices or otherwise

**VI. Full Review Procedures**

**Quorum**

In order to conduct the business of the IRB, it is necessary to maintain a quorum of a simple majority of the membership. A quorum must be maintained when the IRB conducts a full review of a submitted proposal, and one member whose primary concerns are in a nonscientific area must be present.

**Meeting Procedures**

The IRB will meet once per month and will make public its annual meeting schedule. The chair will prepare the agenda for all meetings and will direct the meetings using *Roberts Rules of Order* (current edition). The chair will send members copies of the protocols to be given full review at least five (5) working days before the scheduled meeting.
Should additional meetings be required, members will be notified at least five (5) working days in advance of the meeting. A quorum of the membership is also required to be present in order to conduct business during a special meeting.

Review and Consideration of Protocols

Investigators will submit protocols to the chair of the IRB at least fifteen (15) working days before a scheduled IRB meeting date.

The principal investigator or his/her designee will be present at the portion of the meeting in which his/her proposal is being reviewed. This individual will respond to questions posed by IRB members and clarify relevant portions of the project and/or the protocol.

Members of the IRB are authorized to ask any questions pertaining to the research under review that they deem necessary to reach a conclusion regarding risks, benefits, safety, and protection of human subjects.

Criteria of IRB Approval of Research

In order to approve research, the IRB must determine that all of the following requirements are satisfied:

A. Risks to subjects are minimized
   1. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk;
   2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

B. Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result.

The IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained from the research (for example, the possible effects of the research in public policy) as among those research risks that fall within the purview of its responsibility.

While it is not the responsibility of the IRB to evaluate the scientific, social, or political worthiness of any research project, issues of project design are appropriate for IRB review as the risk to participants increases. Design of the research becomes a determining factor for project approval when the design either directly or indirectly places the participant at
undue risk. The IRB will consider the level of risk involved when the design of the research is not expected to yield meaningful results. If the protocol introduces an element of risk that is not outweighed by the direct benefit to participants, the IRB may consider design when arriving at its decision to approve or reject the project.

C. Selection of subjects is equitable given the purposes and setting of the research.

D. Informed consent will be obtained from each prospective subject or subject’s legally authorized representative in accordance with Federal regulations (45 CFR 46.116.) Informed consent will be appropriately documented in accordance with 45 CFR 46.117. The information that is given to the subject or the representative shall be in language understandable to the subject or his/her legal representative (45 CFR 46.116).

E. As appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

F. As appropriate, there are adequate provisions for monitoring the data collected to ensure safety of subjects.

G. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, or persons institutionalized, or minors, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects. Note that researchers who solicit participants from their classes must be mindful and address the possibility of implicit coercion to participate.

H. The use of deception is sometimes necessary in research involving human subjects. In such instances, the researcher is to consider alternative design and procedures before introducing a deceptive element to the research. When deception is employed, subjects are to be provided a debriefing that clarifies all deceptive elements of the research. Each proposal to the IRB must contain an explanation of the need for deception and a clearly written debriefing statement that subjects will receive at the end of their participation or at the conclusion of the study.

Voting Procedures and Options

Following an adequate period of discussion of the research protocol, the chair will call for a “motion to consider.” At this time any member may make a motion for one of the following options:
Approval  Protocol and consent form(s) are satisfactory as presented, and the investigator may begin the research immediately.

Conditional Approval  Project is not satisfactory as submitted. Investigator must make modifications or alterations to the protocol and/or the consent forms as directed by the IRB. Revisions and modifications made to the satisfaction of the Chair (acting on behalf of the IRB) may then result in approval.

Deferral  There is insufficient information to reach a definitive conclusion regarding the protocol. Investigator will be asked to revise the protocol and resubmit it for full IRB review at a later meeting.

Disapproval  Protocol places subjects at unacceptable risk relative to the benefits of the research. Research project as designed and described is not suitable for involvement of human subjects.

Following the “motion to consider” there will be opportunity for further discussion. The motion can then be seconded and voted upon.

In order for the reviewed research to be approved, it must receive the approval of a majority of those members present.

VII. Notification of IRB Findings

The chair will notify investigators in writing of the findings and actions regarding their protocol within seven (7) working days of the IRB review.

If approved, the investigator may begin the proposed research project upon receipt of notification by the IRB. If conditionally approved, the investigator will be notified of the specific changes to the protocol and/or consent forms(s) necessary to proceed with the research. Until the investigator demonstrates, in writing, that all required changes have been made to the satisfaction of the IRB, the project cannot begin. The letter of notification from the IRB will convey these stipulations and set a time limit. If the investigator does not respond to the IRB’s notification within thirty (30) working days of receiving conditional approval, the proposed project must be resubmitted for consideration at the next regularly scheduled IRB meeting.
If **deferred**, the investigator will be notified in writing and will be asked to resubmit his/her protocol at a scheduled meeting of the IRB. All the findings and recommendations of the IRB will be conveyed in writing to the investigator.

In the event that the research is **disapproved**, notification of the IRB findings resulting in the decision to disapprove will be conveyed in writing to the investigator.

It is up to the investigator to comply with requested changes in order to secure IRB approval. Meeting deadlines and time demands is entirely the responsibility of the investigator.

The IRB has the authority to **suspend or terminate approval** of research that is not being conducted in accordance with the IRB’s requirements or that is being associated with unexpected serious harm to subjects. Suspension or termination decisions will be relayed promptly in writing to the investigator(s), the appropriate university officials, and the appropriate dean and department head.

**VIII. IRB Records**

**A. Minutes of IRB meetings**

According to 45 CFR 46.115, Section 2, the minutes must be written in sufficient detail to show the following:
   a. attendance at the meetings;
   b. actions taken by the IRB, including the number of members voting for or against;
   c. the basis for requiring changes in or disapproving research; and
   d. a written summary of the discussion of controversial issues and their resolution.

In addition the minutes should contain a list of the titles of research and investigators for any **exempt** or **expedited** protocols approved since the last IRB meeting.

A copy of the approved minutes will be maintained in hard copy for a period of five years in the Office for Academic Affairs, and approved minutes will be posted regularly on the university’s IRB web page.

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

**C. Records of continuing review activities.**
D. Annual review reports required of all research projects involving human subjects.

E. Copies of all correspondence between the IRB and the investigators.

F. An annual list of IRB members identified by name, qualifications, and representative capacity.

G. Written procedures for the IRB as described in CFR 45, Parts 46.103 (b) (4) and 46.103 (b) (5).

H. Statements of significant new findings provided to subjects as required by CFR 45, Part 46.116 (b) (5).

The required records will be retained for at least five (5) years and records relating to research that has been conducted must be retained for at least five (5) years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the university at reasonable times and in a reasonable manner.

IX. Procedures for Periodic and Annual Reports

Reporting Procedure for Annual Reports

Annual reports from investigators are due one year after the project approval date, or as specified by the IRB.

Investigators will be informed of impending annual report dates through a memorandum distributed ten (10) months after the approval date of the project (previous annual review for longer termed projects). IRB approved reporting forms will be made available to the investigator(s).

The completed form entitled, Annual Update or Completion Report for IRB Projects, must be submitted to the chair of the IRB within twelve (12) months following the project’s approval date or as designated by the IRB.

Failure to File and Annual Report

If no annual report is filed within thirty (30) calendar days from the IRB directed due date, the investigator will be notified in writing by the chair of the IRB that the approval for the indicated research project has expired and no further work can continue. The investigator will be prohibited from further experimentation involving human subjects. The termination
notice/memorandum will be signed by the chair of the IRB and will be effective from the date of the written notification.

In order to reestablish the expired research project, the investigator must file a new, complete “Request for Review.” This request must be filed with the IRB within thirty (30) calendar days of the receipt of the termination notice/memorandum or the project will remain “officially expired” allowing no further research to be conducted.

Periodic or More-Than-Annual Reports

Occasionally, specific projects will be reviewed more often than annually. Typically, these projects include the following:
1. any research involving fetuses;
2. any research involving human subjects for which there have been reports of injury or unanticipated problems that are consequences of participation in research;
3. any research for which the IRB has specifically required more than an annual review at the time approval of the research project was granted;
4. any research project that the IRB deems appropriate for review on a more-than-annual basis, including projects not included in the categories described above.

Reviews that fall in the more-than-annual categories follow the same reporting and review procedures as indicated for annual reports, with the appropriate changes in reporting intervals and deadlines.

X. Changes in Protocol and/or Consent Forms

Investigators will file with the IRB any substantial change(s) in protocol or consent forms. A copy of the revised protocol and/or consent form along with a letter of clarification must be forwarded to the chair of the IRB no less than fifteen (15) working days prior to the implementation of such change(s). If the proposed change requires FULL or EXPEDITED review, additional time may be required and allotted by the chair of the IRB. No change(s) can go into effect until IRB approval has been obtained in writing.

XI. Report of Injury and/or Unanticipated Problems

Investigators must report to the IRB within seventy-two (72) hours of its occurrence, any injury or unanticipated problem involving risks to subjects or others as a consequence of the research project. In general, anything serious enough to warrant medical or psychiatric intervention is reportable, as are verbal or written complaints from subjects in which they state that
participation presents substantial discomfort, risk, and/or endangerment beyond that explained to them or otherwise stated in the consent form.

Reports of injury and/or unanticipated problems must be filed with the chair of the IRB who, along with the investigator, will report them immediately to the university’s provost. It will be the responsibility of the provost to make any additional administrative notifications.

Access to the code of Federal Regulations Title 45 Part 46 can be obtained at http://www.hhs.gov/ohrp/policy/ohrpregulations.pdf

XII. Human Subject Research Conducted by External Researchers

External researchers who wish to conduct human subjects research at Armstrong are encouraged to find Armstrong faculty sponsors and submit an IRB application that is reviewed through established procedures.

Should an external researcher without Armstrong sponsorship wish to conduct research using Armstrong students or personnel, they must submit a complete IRB application to the IRB chair that is forwarded to the appropriate university vice-presidents or their designees for approval to proceed with the IRB review.

It is recommended that the external reviewer submit IRB approval from their home institution with the Armstrong IRB application, but in no case will an external researcher be able to initiate research at Armstrong without the home institution’s IRB approval in place.

Original Review team: Dr. Donna Brooks, Dr. Patricia Coberly, and Dr. Joyce Bergin

Revised: JRK 11/9/13