

### 3.1 Compliance Regulations and Personal and Institutional Responsibility

The Office of Sponsored Programs shares, with faculty, staff, and administrators, responsibility for assuring Armstrong Atlantic State University's compliance with federal regulations, including those related to misconduct in science, conflict of interest, animal welfare, and the protection of human subjects. Armstrong Atlantic State University's procedures for ensuring compliance with selected regulations appear in the following subsections:

### 3.2 Human Subjects

All research involving human subjects, whether or not it is supported by external funding, must be reviewed and approved by the Armstrong Atlantic State University Institutional Review Board (IRB). IRB approval is required by the Code of Federal Regulations, 45 CFR 46. The Armstrong Atlantic State University Faculty Handbook, Article III Section A.2. refers to the institutional policy, which appears below in section 3.2.a.

#### **Regulations, Article 3, SECTION A.2. Protection of Human Subjects**

Persons conducting research involving human subjects have an ethical as well as professional obligation to ensure the safety, protection and rights of participants. It is the intent of Armstrong Atlantic State University through its Institutional Review Board (IRB) to assist those engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. Armstrong Atlantic State University recognizes its duty and obligation to protect the rights and welfare of human subjects of research regardless of the source of funding. The university has an obligation to ensure that all research involving human subjects meets regulations established by the United States Codes of Federal Regulations (CFR). Procedures and the internal policy regarding the IRB are contained in the *Grants and Contracts Manual for Research and Sponsored Programs*.

IRB membership consists of ten persons including one member who is not otherwise affiliated with Armstrong Atlantic State University, and one member from a discipline not normally associated with research involving human subjects. Membership must constitute a mix of both men and women. Members shall be appointed by the vice president and dean of faculty. The chair will be the dean of the School of Graduate Studies. Other members shall be the associate/assistant deans of arts and sciences, education, and health professions, and the director of Sponsored Programs. The IRB may invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the IRB. These invited individuals may not vote with the IRB.

Note that compliance with 45 CFR 46 and the requirements of the IRB is the responsibility of the project director.

See Appendix C for more information and IRB forms.

### **3.2a Armstrong Atlantic State University Procedures and Internal Policies Regarding the Institutional Review Board (IRB) for the Protection of Human Subjects in Research**

#### **I. Statement of Principles and Purpose**

Persons conducting research involving human subjects have an ethical as well as professional obligation to ensure the safety, protection and rights of participants. It is the intent of Armstrong Atlantic State University through the IRB to assist those engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. Armstrong Atlantic State University recognizes its duty and obligation to protect the rights and welfare of human subjects of research regardless of the source of funding.

The University has an obligation to ensure that ALL research involving human subjects meets regulations established by the United States Codes of Federal Regulations (CFR). It is not the intent of the university or the IRB to interfere in any way with competent, ethical, and sound research involving human subjects. However, the university must ensure that its personnel act in compliance with regulations as well as the 'letter' of these regulations, because the manner in which we conduct research involving human subjects reflects on our professional, personal and community commitments to rigorous ethical and scientific standards of conduct.

It is likely that not all possible contingencies have been foreseen or considered in these guidelines and procedures. The IRB needs the cooperation of the research community of scholars at AASU in establishing the means to assure adequate protection of human subjects. Therefore, the IRB invites input from investigators and interested parties regarding revisions and updates to these guidelines and procedures. Where possible and appropriate, we can develop a streamlined, effective system of review and assurance regarding an ethical and professional environment of human subject research.

IRB "approval" means that the IRB rules that the potential risks to human subjects are, in its opinion, acceptable. It does not mean that a project has departmental or institutional approval and the proper procedures for obtaining such approval should be followed.

#### **II. Definitions**

- A. There is the question of whether a planned activity is 'research' and therefore needs IRB review. The Code of Federal Regulations defines research as "...a systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to generalized knowledge." Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and services programs may include research activities. Other criteria which may be of use in determining 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; and
  - use of experimental drugs or devices.

- B. 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 the 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 participants or to the student investigator; AND
  - it is not genuine research which is expected to result in publication or some other form of public dissemination.

Any student research project not meeting ALL of the above criteria must follow all IRB procedures.

Graduate students completing the thesis, practicum, or project requirement involving human subjects must submit an application to the IRB. The approval notification from the IRB must be included in the appendix of the thesis. Academic units may require the approval notification in the appendix of the practicum or project document.

### III. IRB Membership

IRB membership shall be consistent with regulation §46.107 of the Code of Federal Regulation 45 CFR 46. Membership consists of at least ten persons including one member who is not otherwise affiliated with Armstrong Atlantic State University, and one member from an area not normally associated with research involving human subjects. Membership must constitute a mix of both men and women. Members shall be appointed by the Vice-President and Dean of Faculty. The chair will be the Dean of the School of Graduate Studies. Other members shall be the Assistant Deans of Arts and Sciences, Education, and Health Professions, and the Director of the Office of Sponsored Programs. The IRB may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available to the IRB. These invited individuals may not vote with the IRB.

#### The IRB Chair and Vice-Chair

The IRB Chair shall be the Dean of the School of Graduate Studies with a degree at the doctoral level. Duties of the Chair are described throughout the remainder of this document.

The IRB Vice-Chair shall be an AASU faculty member of the IRB with a degree at the doctoral level. This person shall have all associated responsibilities and obligations of the Chair, whenever the Chair is incapable of serving in that capacity and when the Chair is an investigator on a research project being reviewed or considered by the IRB. The duties and responsibilities of the Vice-Chair are the same as for any IRB member, except when in the authorized capacity of acting chair.

In the event that neither the Chair or Vice-Chair are available to preside at a meeting of the IRB, the IRB members present shall appoint a member to act as chair for that meeting. This person shall have all the responsibilities and duties associated with the office of Chair for that meeting.

Nominations of candidates for Vice-Chair may come from any member of the IRB. Self-nomination is allowed. Nominations are taken from the floor during the first regular IRB meeting of the academic year. Election shall stem from a majority vote of these IRB members present and voting at that meeting. The Vice-Chair shall serve for a period of one year and may be considered for reelection at the end of each term of office.

#### Removal of IRB Members Before Expiration of Appointed Term

In the unlikely event that a member of the IRB should conduct him-herself in a manner inviting consideration for a request for removal from the IRB, such a member of the IRB can be removed from the Board with the direct approval of the Chair of the IRB and no fewer than three additional members of the IRB.

The IRB Vice-Chair can only be removed from office by a majority vote of the full IRB. Anyone removed as Vice-chair retains regular IRB membership for the duration of his/her term.

#### IV. Administrative duties

Research protocols involving human subjects shall be presented to the Chair of the IRB for evaluation and categorization as EXEMPT, EXPEDITED REVIEW, or FULL REVIEW according to procedures detailed in this document.

The primary function of the IRB is to evaluate and review protocols which fall into EXPEDITED REVIEW or FULL REVIEW categories, described below. Duties of the IRB Chair extend into review of all research as well as additional duties described below.

#### V. Initial categorization and review of protocols

The Chair of the IRB shall review all protocols and requests for review to determine which of the following three categories of review is appropriate:

- A. EXEMPT; the investigator is so notified within five (5) working days of protocol submission and the IRB Chair acts to monitor EXEMPT research.
- B. EXPEDITED REVIEW; the protocol is reviewed by at least the Chair of the IRB, or Vice-Chair where appropriate, and one other member of the IRB. Additional members may be asked by the Chair 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 the next scheduled meeting of the IRB. A protocol cannot be disapproved by expedited review procedures.

Investigators will be notified of the findings of an expedited review within fifteen (15) days of protocol submission.

- C. FULL REVIEW; see the following section (Full Review Procedures).

#### VI. Full Review Procedures

##### Quorum

In order to effectively and legally review proposed research not in an EXEMPT or EXPEDITED category, there shall be a majority of the IRB members present, including at least one member whose primary concerns are in nonscientific areas.

##### Meeting Procedures

The IRB will meet once a month, if needed. If additional meetings are needed, members shall be informed at least five (5) working days in advance. Special meetings may be called on shorter notice, but such a meeting must have a majority of IRB members present in order to be official. The Chair shall prepare the agenda and direct the meeting.

Review and Consideration of Protocols

Wherever possible and desirable, the Principal Investigator (or designee) shall be present at that portion of the meeting in which his/her proposal is under consideration, in order to clarify relevant portions of the protocol and project.

Members of the IRB are authorized to ask any questions pertaining to the study in order 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 shall 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 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 in the realm of IRB authority to evaluate the scientific, social, or political worthiness of any research project, issues of project design are an appropriate area of concern as the risk through participation increases. An IRB member must consider design of the research in determining approval if such design either directly or indirectly places the participant at undue risk. The level of risk involved should be considered when the design of the research and procedures involved cannot be expected to yield meaningful data. If the protocol introduces an element of risk that is not outweighed by direct benefit to participants an IRB member may consider design in arriving at a decision.

- 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 the subject's legally authorized representative in accordance with Federal regulations (45 CFR 46.116)

- E. Informed consent will be appropriately documented (in accordance with 45 CFR 46.117). Informed consents are required to be written in “lay language” in accordance with federal regulations (45 CFR 46.116) which states that “The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. For example, the amount of blood drawn may be stated in milliliters (ml) or cubic centimeters (cc), but must also be stated in teaspoons, cups or pints.”(Refer to sample informed consent form)
- F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
- G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- H. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, or persons who are institutionalized, or minors, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- I. The use of deception is sometimes necessary in research involving human participants. In such instances, the researcher is to consider alternative design and procedures before introducing a deceptive element to the research. In addition, participants are to be provided a debriefing which clarifies any deceptive elements of the research as soon as possible. Each proposal to the IRB should contain an explanation of the need of deception and a clearly written debriefing statement that participants will receive at the end of participation.

#### Voting Procedures and Options

After an adequate period of discussion of the research protocol, the Chair may call for a “motion to consider” at which point any IRB member may move for one of the following:

- |             |   |
|-------------|---|
| APPROVAL    | Protocol and consent form(s) are satisfactory as presented, and investigator may begin research immediately;  |
| CONDITIONAL | Project is not satisfactory as submitted. Investigator must make APPROVAL modifications and or alterations to protocol and/or consent form(s) as directed by the IRB. Revisions and modifications to the satisfaction of the IRB Chair (acting on behalf of the IRB) may then result in APPROVAL. |
| DEFERRAL    | There is insufficient information to reach any definitive conclusion regarding the protocol. Investigator will be asked to revise the protocol and resubmit for full IRB review at a later meeting.   |
| DISAPPROVAL | Protocol places subjects at unacceptable risk relative to benefits. 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 and clarification. 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. Tied votes are considered not approved and will be deferred for alterations and modifications necessary to obtain approval.

**VII. Notification of IRB findings**

The IRB Chair shall notify investigators in writing within seven (7) days of the IRB review, of the findings and actions regarding their protocol.

If APPROVED, the investigator may begin the proposed research project.

If CONDITIONALLY APPROVED, the investigator shall be notified of the specific changes to the protocol and/or consent form necessary to proceed with IRB approval of the research protocol. The Chair of the IRB shall communicate, in writing, the findings of the IRB and the necessary modifications. Until the investigator convincingly demonstrates, in writing, that all required changes have been made to the IRB’s satisfaction, the project CANNOT begin.

If the investigator does not respond to the IRB’s notification of required changes within thirty (30) calendar days of receiving CONDITIONAL APPROVAL, the proposed project must be resubmitted for full review consideration at the next regularly scheduled IRB meeting.

The letter of notification to the investigator will convey these stipulations and the time limit.

If DEFERRED, the investigator will be notified in writing that the project as described provides insufficient information to reach a decision for approval or disapproval. The investigator will be asked to resubmit for a later regularly scheduled meeting. In addition, the findings of the IRB that resulted in such a decision will be conveyed to the investigator.

If DISAPPROVED, notification and the findings of the IRB resulting in such a decision will be conveyed, in writing, to the investigator.

In some cases, modifications or alterations to protocol(s) and/or consent form(s) will be required for approval of a research project. Such details will be made in writing at the time of notification. It is up to the investigator to comply with these requested changes in order to obtain approval. Every responsible effort will be made to assist the investigator in bringing a non-approved project into compliance with IRB regulations in order to be approved. However, meeting deadlines and time demands is entirely the responsibility of investigators submitting proposals.

**VIII. Minutes of IRB meetings**

The minutes shall include, among other things:

- A. a record of those members present and voting, as well as an account of business conducted and announcements made;
- B. an accounting of those voting for/against motions, as well as relevant discussion regarding proposals being reviewed.

These minutes shall serve as IRB records of full review proceedings. All remarks, commentaries, opinions, and votes of board members are eligible to become part of the official record of the meeting.

A copy of the minutes and other official IRB records will be kept in the Office of the Dean of Graduate Studies.

IX. Annual reports

All approved ongoing research projects involving human subjects shall undergo an annual review.

Occasionally, selected projects will be reviewed more often than annually. Such projects are:

- A. any research involving fetuses,
- B. any research involving human subjects for which there have been reports of injury or unanticipated problems as a consequence of participating in the research,
- C. any research for which the IRB has specifically required “more than annual” review at the time approval was granted,
- D. any research project the IRB deems appropriate for review on a more-than-annual basis, including projects not in any of the above categories.

“More-often-than annual” reviews shall follow the same reporting and review procedures as indicated for annual reports, with the appropriate changes in reporting intervals and deadlines.

Reporting procedure

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 review dates with a memorandum distributed ten (10) months after approval date (or previous annual review for longer term projects). At that time reporting forms will be made available to relevant investigators.

Complete reports must be submitted to the IRB Chair within twelve (12) months following approval date, or as designated by the IRB.

Failure to file Annual Report

If no annual report is filed within a thirty (30) day (grace) period from the annual report due date, the investigator will be notified in writing that the approval for the indicated research project has expired. The investigator is prohibited from further experimentation involving human subjects in that research project. This termination notice/memorandum shall be signed by the Chair of the IRB and is effective from the date of the written notification.

In order to re-establish that research project, the investigator must file a new and complete “Request for Review”.

X. Changes in protocol and/or consent forms

Investigators shall file with the IRB via the IRB Chair ANY substantive changes in protocol or consent forms. A copy of the revised protocol and/or consent form, along with a letter of clarification shall be forwarded to the IRB Chair no less than 14 days prior to the implementation of such change. If the proposed change requires FULL or EXPEDITED review, additional time

may be required. In any case, the proposed change(s) cannot go into effect until IRB approval has been obtained.

**EXCEPTION:** A protocol may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subject. However, the IRB Chair must be notified **IN WRITING** of such a change within 72 hours and review is required immediately.

All required records will be retained for at least three years after completion of the research.

**XI. Report of injury and/or unanticipated problems**

Investigators must report to the IRB within 72 hours of its occurrence, ANY injury or unanticipated problem involving risks to subjects or others as a consequence of the research project.

Investigators should use their best judgment regarding the nature and degree of a reportable injury or unanticipated problem. In general, anything serious enough to warrant medical or psychiatric intervention is reportable, as are verbal or written complaints of subjects in which they proclaim 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:

Office for Protection of Research Risks  
National Institutes of Health  
Department of Health and Human Services  
Bethesda, MD 20205

Such reports must be signed by the IRB Chair and filed as soon as possible from the date of occurrence.

**XII. Consequences of non-compliance**

All research involving human subjects **MUST** have IRB review and approval before such research can be initiated. Research that is conducted without IRB approval must be terminated immediately. Investigator(s) associated with such research must file for IRB review and approval before restarting the research project.

Investigators who continue non-approved research should note that such non-compliance will be reported to the appropriate administrators.

Failure to comply with IRB directives, regulations and procedures including annual reports, changes in protocol, consent forms, and other requests for information or compliance emanating from the IRB Chair will result in the following:

**Project termination:** Investigators and their staff and assistants are prohibited from involving human subjects in that research project until formal IRB approval/reinitiation is obtained. Such approval may be sought at the next available regularly scheduled meeting of the IRB, or at a special meeting called at the discretion of the IRB Chair.

**Interruption of Research Support:** An additional consequence of non-compliance can be the interruption of grant funds (internal or extramural in origin) allocated to that research project.

Such “freezing of funds” will continue until the project and its investigators are in compliance according to regulations as determined by the IRB.

Report to Appropriate Federal Agencies: In some cases, the university is required to report to the Office for the Protection of Research Risks (OPRR) any termination of a project due to non-compliance with IRB regulations and directives. Further, such non-compliance is reportable to the Federal Agency supporting the non-compliant research project.

### XIII. Investigatory Rights

In order to determine that all substantive and relevant changes in protocol and/or consent documents are being reported, and in order to verify compliance with IRB regulations, the IRB shall have the authority to physically inspect any research premises or review non-confidential research documents relating to the protocol and procedures being used in human subject experimentation. Generally, the investigator will be asked to provide copies of relevant and necessary documents for IRB review. Such document requests are in addition to those generated in an annual review process. In most cases, this will only occur when there is an indication that a substantive change is in effect which has not been reported. Failure to comply with such an IRB request for information may result in suspension or termination of IRB approval of research.

### XIV. Suspension or termination of IRB approval of research

According to 45 CFR 46.113:

“An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s actions and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary (of OPRR).”

### XV. Appeal procedures

There are no formal appeal procedures associated with IRB review. The IRB is not a judicial body, but a review board embodied to consider and uphold the rights, welfare and protection of human subjects in research. IRB approval for research which has been suspended or terminated can be reinstated with a demonstration that the protocol/project can secure IRB approval. Similarly, a disapproved project need only be altered so that it can secure approval. An appeal process assumes that the decision of the IRB can be overturned by another group. An IRB ruling is not subject to appeal nor can it be overturned by another group or person(s). (Please note that IRB approval only means that the IRB rules that the potential risks to the subject are, in its opinion, acceptable. IRB approval DOES NOT mean that a project has institutional approval, and the proper procedures for obtaining such approvals should be followed.) Only the IRB can alter its previous determination. According to 45 CFR 46.112:

“Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.”

### XVI. Adoption of the Ten Ethical Principles of the APA

In addition to the preceding policies and procedures the AASU Institutional Review Board also adopts the ten ethical principles of the APA regarding the conduct of research with human participants and the ongoing responsibilities of all investigators.

- A. In planning a study the investigator has the personal responsibility to make a careful evaluation of its ethical acceptability, taking into account these Principles, for research with human beings. To the extent that this appraisal, weighing scientific and human values, suggests a deviation from any Principle, the investigator incurs an increasingly serious obligation to seek ethical advice and to observe more stringent safeguards to protect the rights of the human research participant.
- B. Responsibility for the establishment and maintenance of acceptable ethical practice in research always remains with the individual investigator. The investigator is also responsible for his ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom, however, incur parallel obligations.
- C. Ethical practice requires the investigator to inform the participants of all features of the research that reasonably might be expected to influence willingness to participate and to explain all other aspects of the research about which the participant inquires. Failure to make full disclosure gives added emphasis to the investigator's responsibility to protect the welfare and dignity of the research participants.
- D. Openness and honesty are essential characteristics of the relationship between investigator and research participant. When the methodological requirements of a study necessitate concealment or deception, the investigator is required to ensure the participant's understanding of the reasons for this action and to restore the quality of the relationship with the investigator.
- E. Ethical research practice requires the investigator to respect the individual's freedom to decline to participate in research or to discontinue participation at any time. The obligation to protect this freedom requires special vigilance when the investigator is in a position of power over the participant. The decision to limit this freedom increases the investigator's responsibility to protect the participant's dignity and welfare.
- F. Ethically acceptable research begins with the establishment of a clear and fair agreement between the investigator and the research participant that clarifies the responsibilities of each. The investigator has the obligation to honor all promises and commitments in the agreement.
- G. The ethical investigator protects participants from physical and mental discomfort, harm, and danger. If the risk of such consequences exists, the investigator is required to inform the participant of that fact, secure consent before proceeding, and take all possible measures to minimize distress. A research procedure may not be used if it is likely to cause serious and lasting harm to participants.
- H. After the data are collected, ethical practice requires the investigator to provide the participant with a full clarification of the nature of the study and to remove any misconceptions that may have arisen. Where scientific or human values justify delaying or withholding information, the investigator acquires a special responsibility to assure that there are no damaging consequences for the participant.

- I. Where research procedures may result in undesirable consequences for the participant, the investigator has the duty to detect and remove or correct these consequences, including, where relevant, long-term aftereffects.
- J. Information obtained about the research participants during the course of an investigation is confidential. When the possibility exists that others may obtain access to such information, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to the participants as a part of the procedure for obtaining informed consent.

XVII. Enactment

These procedures and policies are considered to be in effect immediately upon approval by authorized university officials and remain in effect and enforceable until otherwise amended or repealed.

Approved April 27, 1995. Amended September 22, 1995, November 2, 1995, July 25, 1996, March 2, 2000 and July 24, 2000.

### 3.3 Animal Welfare

All Armstrong Atlantic State University activities involving the care or use of vertebrate animals are subject to compliance with the federal Animal Welfare Act, whether or not such care or use is supported by external funding. The primary purpose of the Act is to ensure that animals used in research, for exhibition, or as pets, receive humane care and treatment. The law's regulations cover the transport, purchase, sale, housing, care, handling, treatment, and disposal of such animals. There are numerous regulations and guides which should be familiar to people managing animal research. Two of the most important are:

Federal Animal Welfare Act (AWA) -- first passed in 1966 and amended three times since, applies to ALL institutions which conduct research using WARM-BLOODED animals (i.e., dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, marine mammals, livestock used for biomedical research, and warm-blooded animals). EXCLUDES: rats, mice and birds (85-90 percents of the animals used in research), and farm animals as well as cold-blooded animals. AWA requires that all institutions using warm-blooded animals are subject to annual inspections by USDA officials AND must have an Institutional Animal Care and Use Committee (IACUC).

Public Health Service Policy on Humane Care and Use of Laboratory Animals -- has been in existence for many years (last revised in 1986). It requires ALL institutions receiving PHS funding involving the use of vertebrate animals, to adhere to the provisions of this policy, regardless of the species of vertebrate animal used. (INCLUDES cold-blooded animals, and ALL warm-blooded animals, even rats, mice and birds).

**At present, Armstrong Atlantic State University does not have an Institutional Animal Care and Use Committee (IACUC).**

**Research requiring approval is reviewed by the Georgia Southern University/ACUC. Contact the OSP for more information. Your compliance with this regulation will be documented by your signature on the Armstrong Atlantic State University Approval to Submit Proposal for External Funding form.**

### 3.4 Policy for Addressing Allegations of Misconduct in Scientific and Scholarly Research

#### Regulations, SECTION A.3. Misconduct in Science

Armstrong Atlantic State University has long embraced the principle that honesty is an essential component of scholarly activity. Principal investigators and others in positions of responsibility for the conduct of research and scholarly activity are expected to exercise reasonable supervision of those under their direction to ensure the integrity of the research or scholarly activity being conducted.

The university assumes primary responsibility for investigating and resolving allegations of scientific and scholarly misconduct by its campus community. This responsibility holds regardless of whether the activity involved was funded by external agencies. Assumption of this responsibility is consistent with the Code of Federal Regulations (CFR) at 45 CFR 689, though in some cases federal reporting requirements also pertain. The policy/procedure for investigating and resolving allegations of misconduct in science is contained in *Grants and Contacts Manual for Research and Sponsored Programs*.

Armstrong Atlantic State University has long embraced the principle that honesty is an essential component of scholarly activity. Principal Investigators and others in positions of responsibility for the conduct of research and scholarly activity are expected to exercise reasonable supervision of those under their direction to ensure the integrity of the research or scholarly activity being conducted.

The university assumes primary responsibility for investigating and resolving allegations of scientific and scholarly misconduct by its campus community. This responsibility holds regardless of whether the activity involved was funded by external agencies. Assumption of this responsibility is consistent with the Code of Federal Regulations (CFR) at 45 CFR 689, though in some cases federal reporting requirements also pertain.

#### Definition of misconduct in scientific and scholarly research

For the purposes of these procedures, misconduct in scholarly research is defined as:

- 1) fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scholarly community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data;
- 2) retaliation of any kind against a person who reported or provided information about suspected alleged misconduct and who has not acted in bad faith.” (*National Science Foundation Dear Colleague Letter, August 16, 1991*).

#### Reporting and confidentiality

It is difficult to balance the need to preserve the confidentiality of those persons bringing allegations of scientific and scholarly misconduct with the rights of persons to have knowledge of their accusers. Too little protection for those bringing allegations discourages legitimate reporting, and too secretive a process endangers the researcher against whom allegations are made.

It must be recognized that a researcher’s reputation is paramount to his/her career, and that serious consideration must be given before anyone takes action to impair that reputation. Just as care must be taken to ensure that those filing legitimate allegations in good faith are protected from reprisals, the

university will not tolerate actions of this nature that are taken without foundation and/or with malicious intent.

To ensure both the opportunity to make reports and the internal protection of those reporting, the identity of the person filing the allegation of misconduct shall be kept confidential during the inquiry state of this procedure, unless that person consents to the release of his/her name. Similarly, those accused of such acts are entitled to have all proceedings handled in confidence. However, the university is also required to comply with the Open Records Act and, should these come into conflict, the law will prevail. The university will not tolerate retaliation against those filing reports under this policy.

### **Receipt of Allegations and Inquiry**

Allegations of scientific or scholarly misconduct should be reported within a department to the department head. In the case of a conflict of interest on the part of the department head or dean, the allegations should be reported to the Vice President and Dean of Faculty. All allegations shall be made in writing and forwarded, through the dean to the Vice President and Dean of Faculty.

Upon receipt of a written allegation, the Vice President and Dean of Faculty shall initiate an inquiry into the allegation. After discussing the matter with the party raising the issue, the Vice President and Dean of Faculty shall inform the accused person that an allegation of misconduct has been made, and provide that person with a copy of the written allegation. The person accused will be given a reasonable amount of time in which to respond to the allegation. The Vice President and Dean of Faculty may seek advice at this stage of the inquiry to evaluate the validity of the allegation.

Depending upon the nature of the discipline and the accusation made, it may be necessary for the original databooks or other laboratory material to be captured to ensure the accuracy of the original record. The Vice President and Dean of Faculty is authorized to obtain all records he deems necessary to safeguard the records. Faculty and staff are required to release these records upon request. The Vice President and Dean of Faculty will be responsible for safeguarding the records and, in cases where the records are necessary for the continuation of the research, will provide copies for use by investigators.

The Vice President and Dean of Faculty, in consultation with the appropriate school dean, shall determine within 30 days, on the basis of the inquiry, whether or not to initiate an investigation. In circumstances which require more time, this timeline may be extended for a reasonable period. Should it be determined that no reasonable basis exists to initiate an investigation, the party making the allegation, the person against whom the allegation is made, the dean, and department head, shall be so informed. The Vice President and Dean of faculty will maintain the record of inquiry, apart from the faculty or staff member's personnel file, or the student's graduate record.

Should the person bringing the allegation be dissatisfied with the closure of the matter, he/she may request, within 30 days of notice of closure, that the President review the matter. Should the President concur with the decision, the matter will be closed. Should the President not concur, he will advise the Vice President and Dean of Faculty to initiate an investigation.

### **Investigation**

Should an investigation be warranted, an ad hoc advisory committee will be appointed of at least three scholars who have no responsibility for the activity under inquiry, who can be impartial, and who have no interests which would conflict with the university's interest in securing a fair and thorough inquiry. The inquiry committee may, but need not, include individuals from outside the university. The Committee will operate in executive session.

The Committee's responsibility is to examine all pertinent information, review all records, and take such testimony as necessary. The committee shall allow the person against whom the allegation is made an opportunity to respond to the allegation and information collected. The accused person may be accompanied by legal council if he/she desires. However, because this is an allegation of scientific or scholarly misconduct, the faculty member is expected to participate fully in the process.

The Committee shall provide the Vice President and Dean of Faculty, and the individual against whom the allegation was made, a written report including findings of fact, a preliminary determination, and any recommendations based on these facts within 90 calendar days of its appointment. This timeline may be extended when deemed necessary and reasonable.

After receipt of the report, the Vice President and Dean of Faculty, in consultation with the school dean, will make his/her decision.

- a) If it is determined that no scholarly or scientific misconduct has occurred, the matter will be closed, and the following actions taken:
  - i) The person making the allegation and the accused researcher will be notified of the decision.
  - ii) The researcher will be consulted to determine what actions, if any, should be taken to ensure that the researcher's reputation is secured, and implementation of those actions, including issuing statements of exoneration, if required.
  - iii) The appropriate federal agency or other funding agency will be notified of the outcome of the investigation.
- b) If it is determined that scientific or scholarly misconduct has occurred and that further action is warranted, the Vice President and Dean of Faculty will take the following actions:
  - i) If the action is against a faculty member, deliver to the appropriate dean a written report stating that reasonable cause exists to adjudicate charges of wrongdoing brought against the faculty member, with enough of the underlying facts to provide reasons for this conclusion.
  - ii) If the action is against a professional or classified staff member, deliver a statement of the basis of the decision and notice of appropriate disciplinary or dismissal action in accordance with the applicable professional or classified staff rules.
  - iii) If the action is against a student, deliver a statement of the basis for the decision and notice of appropriate disciplinary or dismissal action in accordance with the University Student Code.

In all situations, the dean of the appropriate college shall be notified.

### **Notifying funding agencies and other outside entities**

The Vice President and Dean of Faculty is responsible for notifying appropriate federal or other granting agencies of outcomes of inquiries, that an investigation has been initiated, and the results of any investigation, as that agencies rules may require. The Vice President and Dean of Faculty is authorized to take such actions, in consultation with the college dean, as are necessary or prudent to ensure the protection of the university and the funds of the granting agency during the period of inquiry, investigation, or any resulting adjudication. In addition, the Vice President and Dean of Faculty may require that other actions be taken, such as notification of editors or publishers if the work has been published, to ensure the integrity of the scholarly process.

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Your compliance with this regulation will be documented by your signature on the Armstrong Atlantic State University Approval to Submit Proposal for External Funding form.

The Faculty Handbook - Regulations, Section A.3 refers.

### **3.5 Lobbying**

For each application for federal funding over \$100,000, the university is required to certify that (1) no federal funds were or will be used to attempt to influence, or lobby for, the awarding of that funding; and (2) we will disclose the relevant information if we have used, or intend to use, non-federal funds to pay for the lobbying activities of an individual or organization not regularly employed by Armstrong Atlantic State University.

### 3.6 Conflict of Interest Policy Pertaining to Sponsored Projects

*Summary: This policy sets forth procedures and guidelines that are to be followed in resolving actual and potential faculty conflicts of interest and commitment pertaining to sponsored projects. This policy applies to all sponsored projects funded by A) commercial sponsors, B) those federal agencies having specific conflict of interest requirements, and C) purchase orders and subcontracts issued by Armstrong Atlantic State University on behalf of sponsored projects, irrespective of the source of funds.*

#### **Regulations, SECTION A.4. Conflict of Interest**

The policy contained in the *Grants and Contracts Manual for Research and Sponsored Programs* sets forth procedures and guidelines that are to be followed in resolving actual and potential conflicts of interest and commitment pertaining to sponsored projects. This policy applies to all sponsored projects funded by a) commercial sponsors, b) those federal agencies having specific conflict of interest requirements, and c) purchase orders and subcontracts issued by Armstrong Atlantic State University on behalf of sponsored projects, regardless of the source of funds.

The university and its faculty often benefit from the faculty's participation in both public and private outside activities. The university has no interest in setting forth detailed rules that may interfere with faculty members' legitimate outside interests.

Faculty members, in turn, must also ensure that their outside obligations, financial interests, and activities do not conflict or interfere with their commitment to the university. This obligation pertains to both full-time and part-time faculty.

The areas of potential conflict may be divided into two categories. Conflicts of Interest are defined as situations in which faculty members may have opportunity to influence the university's business decisions in ways that could lead to personal gain or give improper advantage to members of their families or to associates. Conflicts of Commitment are defined as situations in which faculty members' external activities interfere or appear to interfere with their paramount obligations to their students, colleagues, and the university.

In those circumstances in which the university is engaged in or intends to engage in a sponsored project with a commercial organization under one of the university's sponsored projects, a conflict of interest may occur when a faculty member's affiliation with the external organization meets any of the following criteria:

- a) The faculty member is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization or corporation either funding a sponsored project or providing goods and services under a sponsored project on which the faculty member is participating in any capacity.
- b) The faculty member is the actual or beneficial owner of more than five percent (5%) of the voting stock or controlling interest of such organization or corporation.
- c) The faculty member has dealings with such organization or corporation from which he or she derives income of more than \$10,000 per year, exclusive of dividends and interest.
- d) The faculty member's immediate family (spouse, parents, parents-in-law, siblings, children, or other relatives living at the same address as the faculty member) meet any of the criteria stated in a)-c) above.

Each faculty member participating in a sponsored project covered by this policy must disclose whether or not he or she has external affiliations that may constitute a conflict by falling within the criteria

stated in paragraphs a-d above. A disclosure must be completed prior to the university's acceptance of the sponsored project or issuance of a purchase order or subcontract for the acquisition of goods and services.

The disclosure form (Attachment 1) is to be sent to the OSP via the faculty member's department chair or dean. Positive disclosures will be reviewed by the Council of Deans.

In reviewing the positive disclosures, the Committee will be guided by the following practices and apply them as may be appropriate:

- a) Assure adherence to relevant university policies and other university documents that they deem appropriate.
- b) Consider the nature and extent of the financial interest in the relationship of the faculty member and the external organization.
- c) Give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation.
- d) Consult with and obtain additional information from the faculty member as either the Committee, or the faculty member feel may be helpful in resolving actual or potential conflicts.
- e) Act in a timely manner so as not to delay unduly the conduct of the sponsored project.
- f) Conclude that the university may take one of the following actions:
  1. Accept the sponsored project award.
  2. Do not accept the sponsored project award.
  3. Accept the sponsored project subject to suitable modifications in either the sponsored project award document or the external organizational affiliation(s) of the faculty member or faculty member's family.

If the faculty member is dissatisfied with the review conclusion, the faculty member may appeal to the Vice President and Dean of Faculty who will consult with the faculty member and the Research and Scholarship Committee as deemed necessary and appropriate to the particular circumstance. The decision of the Vice President and Dean of Faculty shall be final.

Violations of this policy, such as willful concealment of financial interests, may result in sanctions being imposed upon the violating individual. The Research and Scholarship Committee will review allegations of violations and will make recommendations regarding the imposition of sanctions to the Vice President and Dean of Faculty.

The **OSP** shall maintain the records pertaining to each disclosure in strict confidence while complying with Georgia's Open Record Law. Access to such records will be limited to the faculty member, the Research and Scholarship Committee, the Vice President and Dean of Faculty, and others who have a legal right to review the records.

*Certain sponsors, particularly federal agencies, may differ from this policy with regard to the timing and frequency of faculty disclosures and other provisions as well. In the case of such discrepancies, the sponsor's requirements will generally prevail.*

## Appendix

The following list of examples serves as a set of guidelines for identifying potential conflicts of interest and commitment. It is not intended as a comprehensive list of all potential situations that could present faculty members and the university with difficulty.

1. Activities that present the potential for conflict.
  - a) Relationships that might enable a faculty member to influence the university's dealings with an outside organization in ways leading to personal gain or improper advantage for the faculty member, or his or her associates or family members. For example, a faculty member or family member could have a financial interest in an organization with which the university does business and could be in a position to influence relevant business decisions. Ordinarily, making full disclosure of such relationships and making appropriate arrangements to mitigate potential conflicts of interest would resolve such problems.
  - b) Situations in which the time or creative energy a faculty member may devote to external activities appear substantial enough so as to compromise the amount or quality of his or her participation in the instructional, scholarly, or administrative work of the university.
  - c) Situations in which a faculty member directs students into a research area from which the faculty member may realize a financial gain. In such situations, the ability of a faculty member to render objective, independent judgment about the students' scholarly best interests may be diminished.
2. Activities that are very likely to present unacceptable conflicts.
  - a) Situations in which a faculty member assumes executive responsibilities for an outside organization that might seriously divert his or her attention from university duties. Faculty members should consult with the appropriate dean before accepting any outside management position.
  - b) Use for personal profit of unpublished information emanating from sponsored agreements or confidential university sources, or assisting an outside organization by giving it exclusive access to such information; or consulting with outside organizations that impose obligations upon the faculty member or the university that conflict with the Board of Regent's Intellectual Property Policy or with the university's obligations under sponsored projects.
  - c) Circumstances in which a substantial body of research that could and ordinarily would be carried on within the university is conducted elsewhere to the detriment of the university and its legitimate interests.
  - d) Any activity that a faculty member may wish to undertake on an individual basis that a) involves or appears to involve the university significantly through the use of these resources, facilities, or the participation of academic colleagues, students, and staff, b) involves the use of the university's name or implied endorsement, or c) violates any of the principles set forth in any university policy.

Officially Approved: 10/12/95

Your compliance with this regulation will be documented by your signature on the Armstrong Atlantic State University Approval to Submit Proposal for External Funding form. Should you need to declare a potential conflict of interest or commitment, please use the form, Armstrong Atlantic State University Faculty Disclosure Statement Regarding External Affiliations. Both of these forms may be found in Appendix E of this manual.



### **3.7 Drug Free Workplace/Campus/Community**

As part of its commitment to a drug-free campus, Armstrong Atlantic State University complies with the Drug-Free Schools and Communities Act, as well as a number of Georgia statutes and federal, state, and local laws. Refer to Section G of the Regulations (page R-78) in the University Faculty Handbook. For more information, contact the Assistant to the Vice President for Student Affairs or the Director of Human Resources.

### **3.8 Intellectual Property**

As a unit of the University System of Georgia, Armstrong Atlantic State University must comply with the Intellectual Property Policy established by the Board of Regents, and published in The Policy Manual, Section 603.

#### **Intellectual Property Policy - Pending Approval by Board of Regents**

October, 2000

##### **I. PREAMBLE**

Armstrong Atlantic State University, hereinafter referred to as the University, is dedicated to teaching, scholarship, and the extension of knowledge to the public. Personnel at the University recognize as two of their major objectives the production of new knowledge and the dissemination of both old and new knowledge. Inherent in these objectives is the need to encourage the production of creative and scholarly works and the development of new and useful materials, devices, processes, and other inventions, some of which may have potential for commercialization. Such activities contribute to the professional development of the individual faculty and staff members involved, enhance the reputation of the University, provide additional educational opportunities for participating students, and promote the general welfare of the public at large.

Such creative and scholarly works and inventions which have commercial potential may be protected under the laws of various countries that establish rights called Intellectual Property, a term that includes patents, copyrights, trade secrets, trademarks, plant variety protection, and other rights (definitions are provided in Section V of this document). Such Intellectual Property often comes about because of activities of the University's faculty and other employees who have been aided wholly or in part through use of facilities of the University. It becomes significant, therefore, to ensure the utilization of such Intellectual Property for the public good and to expedite its development and marketing. The rights and privileges, as well as the incentives, of the authors, creators, or inventors hereinafter referred to as the "Originators" must be preserved so that the use of their abilities and the abilities of others at the University may be further encouraged and stimulated.

The Board of Regents of the University System of Georgia has established an Intellectual Property Policy which stipulates that: "Each institution of the System is required to develop policies and procedures for the administration of this Intellectual Property Policy." Therefore, in order to establish the respective rights and obligations of the University, its faculty, students, and other employees in Intellectual Property of all kinds now and hereafter existing and of all countries, regions, or other political entities, the University hereby establishes this Intellectual Property Policy.

##### **II. RIGHTS AND EQUITIES IN INTELLECTUAL PROPERTY**

### **A. Sponsor-Supported Efforts**

Sponsored project agreements with the University or its foundation often contain specific provisions with respect to ownership of Intellectual Property developed during the course of such work, in which case the terms of the sponsored project agreement shall establish ownership. When the sponsored project agreement is silent on the matter, all rights in intellectual property shall vest in the University. Income, if any, from such Intellectual Property shall be shared with the Originator, subject to the sponsor's requirements, in accordance with Section III.J.

### **B. University-Assigned Efforts**

Ownership of Intellectual Property developed as a result of University-assigned efforts shall reside with the University. Copyrightable works created by an employee in the course of his/her employment are considered to be works made for hire under copyright law, with ownership vested in the employer. However, any income from such Intellectual Property shall be shared with the Originator, in accordance with Section III.J. The above notwithstanding, a faculty member's or student's general obligation to produce scholarly and creative works does not constitute a work for hire or a specific University assignment.

### **C. University-Assisted Individual Effort**

Ownership of Intellectual Property developed by faculty, staff, and students who make more than purely incidental use of University resources shall be shared by the Originator and the University. For purposes of this Intellectual Property Policy, the use of the following University resources generally shall not result in shared ownership: all resources available to the public without charge; University-owned/leased office space or equipment; computer equipment; library resources, including electronic resources; and Internet access.

Use of the following University resources in the production of Intellectual Property generally shall constitute more than purely incidental use, shall be defined as University-Assisted Individual Effort, and shall result in shared ownership of the Intellectual Property under this Section: significant resources provided by University-funded and/or University Foundation-funded grants, and stipends; University employees (other than faculty) within the employment period; long distance telecommunication services and other cost-added supplies and services; and University facilities other than offices and the library.

Income, if any, from such Intellectual Property shall be shared as described in Section III.J.

### **D. Individual Effort**

Ownership of Intellectual Property developed by faculty, staff, and students of the University shall reside with the Originator of such Intellectual Property provided that: the Intellectual Property was not developed in accordance with the terms of a sponsored project agreement (see Section II.A); the Intellectual Property was not developed by faculty, staff, or students as a specific University assignment (see Section II.B); and there was no significant use of University resources in the creation of such Intellectual Property (see Section II.C). The Originator of the Intellectual Property shall have the opportunity to demonstrate that this classification applies.

### **E. Other Efforts**

Ownership of Intellectual Property developed by faculty, staff, and students of the University under other efforts is determined according to the criteria specified in Sections II.A. through II.D. above. Such efforts include, but are not limited to, consulting for outside organizations, collaborating with non-University personnel, or serving on non-University boards, committees, task forces, etc. Any agreement should include a statement that the faculty member has intellectual property obligations to the University and this Intellectual Property Policy should be attached to the agreement. In the event that there is any conflict between the University personnel's obligations to this Intellectual Property Policy and their obligations to the entity or collaborative arrangement for which they provide these efforts, the obligations to this Intellectual Property Policy shall control.

### **III. ADMINISTRATIVE PROCEDURES**

#### **A. Responsibility and Organization**

The administration of the principles and policies set forth in this document is the responsibility of the Vice President and Dean of Faculty, whose office shall do so with the advice of the University Intellectual Property Committee and a University legal advisor. The Intellectual Property Committee shall be appointed by the President and consist of no less than five, nor more than nine, members. One of these members shall be designated by the President to serve as Chair. The committee shall include representatives of the Vice President and Dean of Faculty, the Vice President for Business and Finance, and the Faculty Executive Committee. The Chair may add ad hoc members as necessary.

The Intellectual Property Committee will review current procedures and practices and make recommendations for future directions; resolve conflicts of interest; arbitrate decisions concerning intellectual property, and mediate and resolve any disputes between the University and Originators. Care will be taken to include representation on the committee from areas with major and consistent involvement with intellectual properties.

#### **B. Disclosure of Intellectual Property**

For circumstances meeting the criteria for II.A. through II.C., University personnel shall promptly provide the Vice President and Dean of Faculty with a disclosure describing their creative and scholarly works and new material, devices, processes, or other inventions which may have commercial potential. University personnel shall also cooperate with the Office of Academic Affairs and sign all papers deemed by that office reasonable and necessary to protect and commercialize Intellectual Property covered by this Intellectual Property Policy. The Name of the University should be used in an Originator's title to show institutional affiliation in connection with University-related work made public. However, the name of the University and/or Originators may not be used for promotional purposes of a commercial nature without the written approval of the Vice President and Dean of Faculty.

Disclosures are not required for circumstances meeting the criteria delineated in Section II.D. or for works of authorship where there is no intent to commercially exploit the intellectual property (examples include, but are not limited to, articles for publication in scholarly or professional journals and instructional or research material for internal use), even though the ownership of the copyright may reside in the University as determined by Sections II.A., II.B., or II.C. In cases where disclosure is not required, the University shall assign the copyright to the author for publication purposes.

#### **C. Obligations of Principal Investigators/Project Directors**

Principal Investigators/Project Directors shall be responsible for informing coworkers of their rights and obligations under contracts, grants, and the like before the initiation of research or other sponsored projects.

#### **D. Confidentiality**

Certain contractual obligations and governmental regulations require that information be maintained in confidence. Some works, such as certain computer software, may best be protected and licensed as trade secrets. Additionally, inventions must be maintained in confidence for limited periods to avoid the loss of patent rights. Accordingly, the timing of publications is important, and University personnel shall use their best efforts to keep the following items confidential (to the extent allowed by law): all information or material designated confidential in a contract, grant, or the like; all information or material designated or required to be maintained as confidential under any applicable governmental statutes or regulations; and all information relating to Intellectual Property developed by University personnel which may be protected under this Policy until application has been made for protection.

#### **E. Collaboration**

Collaboration between University personnel and persons not employed or associated with the University, including researchers at other universities or companies, can result in the development of Intellectual Property jointly owned by the University and other persons or their employers. Protection and commercialization of such joint Intellectual Property can be difficult without extensive cooperation and agreement among the owners. Accordingly, it is important for University personnel involved in, or contemplating collaborative activities that may result in, the development of Intellectual Property to advise their immediate supervisors and the Office of Academic Affairs of such activities.

#### **F. Administration of "Sponsor-Supported Efforts" (II.A.) and "University-Assigned Efforts" (II.B.)**

The Intellectual Property Committee has the responsibility to evaluate Intellectual Property developed through Sponsor-Supported Efforts and University-Assigned Efforts, and to determine whether to administer such Intellectual Property by undertaking those efforts it determines to be appropriate to protect and license or otherwise commercialize such Intellectual Property.

#### **G. Administration of "University-Assisted Individual Effort" (II.C.)**

Any Intellectual Property which is the result of University-Assisted Individual Effort, shall be administered by the Originator unless the Originator and the Committee agree to have it administered by an entity of the University. Such Intellectual Property which is administered by the University shall be treated as "University-Assigned Effort" (II.B.) Intellectual Property and shall require the Originator to assign to the University his/her share of the ownership rights in such Intellectual Property, but the Originator shall retain the right to a division of revenue as prescribed by section III. J. of this Policy.

#### **H. Administration of "Individual Effort" (II.D.)**

Intellectual Property which is administered by the Originator shall be assigned to the Originator under a simple agreement which provides for periodic reports describing the Originator's administrative activities, generation of payments or royalties, and if appropriate, payment to the University of a portion of net revenue from the exploitation of the Intellectual Property. "Individual Effort" Intellectual Property may be assigned to the University to be treated and administered as University-Assigned Effort (II.B.) Intellectual Property if both the Committee and the Originator agree to do so (see the discussion in Section III.G.).

#### **I. Declined Intellectual Property**

Whenever the University chooses not to administer Intellectual Property or chooses to cease administering Intellectual Property, such Intellectual Property, subject to any obligations to a sponsor, may be released to the Originator to dispose of as the Originator sees fit. The release of such Intellectual Property must be approved by the President.

**J. Revenue Sharing with Originators**

The proposed division of net revenue is presented below. Net revenue is defined as gross receipts received by the University from license activity minus contract amounts due sponsors, if any, and the out-of-pocket costs incurred by the University in protecting and licensing the Intellectual Property:

**REVENUE DISTRIBUTION**

	Originator	Originator's Department	Originator's Research Program	Faculty Development, Internal Grants Program
SPONSOR SUPPORTED	75%	10%	5%	10%
UNIVERSITY ASSIGNED	65%	15%	5%	15%
UNIVERSITY ASSISTED	65-90%	Remainder split equally between the three areas		
INDIVIDUAL EFFORT	100%			
OTHER EFFORTS	To be determined on a case-by-case basis.			

The Originator's share of net revenue shall be divided (equally) among joint Originators of jointly developed Intellectual Property unless a written statement signed by all joint Originators which provides for a different distribution is filed with the University prior to the first distribution of shared net revenue. The percentage for the Originator's Department should be used to fund Research and Scholarship activities.

The percentage for the Originator's Research Program applies only while the Originator is employed by, and conducting research at, the University. If this is not the case, this share is reallocated to the Faculty Development, Internal Grants Program.

In the event the Intellectual Property is licensed to the Originator, or the Originator has a significant financial interest in an external entity which holds license rights, the Originator shall waive the right under the University Intellectual Property Policy to receive the Originator's share of royalties identified above (except when the development of the Intellectual Property meets the criteria established for the Individual Effort category, in which case this clause does not apply).

In the event the Originator does not receive the Originator's share, that share shall be distributed to the other parties in the proportions detailed above.

In the event the terms of the license of the Intellectual Property provide the University with equity, or an option to acquire equity, in the entity which licenses the Intellectual Property, the share of such equity due to Originators as identified above will be distributed to the originators when such equity is transferable or convertible to cash.

Under both of these circumstances, either the Originator or an entity in which he/she has a significant financial interest already is taking a significant share of the royalties "off the top."

### **K. Interpretation, Decision, and Appeal**

Cases where the Originator and the University agree to the classification and proposed mechanism of commercialization of the Intellectual Property will be processed by the University in accordance with this policy. All cases in which questions arise as to equities, rights, division of royalties, or any other Intellectual Property-related matter shall be referred to the Intellectual Property Committee for consideration, interpretation and application of policy, and decision. Appeal of an Intellectual Property Committee decision shall be to the Vice President and Dean of Faculty, then to the President, and, finally, to the Board of Regents. Appeals within the University must be made in writing within sixty (60) days of written notice of a final decision. Appeals to the Board of Regents shall be made in accordance with Article IX of the Bylaws of the Board, which requires that all appeals be filed within twenty (20) days of the final decision of the President of the University.

## **IV. PREVAILING POLICY AND HEIRS AND ASSIGNS**

### **A. Prevailing Policy**

In the event of conflicts between the Intellectual Property Policy of Armstrong Atlantic State University and the Intellectual Property Policy of the Board of Regents of the University System of Georgia, the Intellectual Property Policy of the Board of Regents shall prevail.

### **B. Heirs and Assigns**

The provisions of this Policy shall fix the interests of and be binding upon the heirs and assigns of (1) all University personnel and (2) all others who agree to be bound by it.

## **V. DEFINITIONS**

Intellectual Property shall be deemed to refer to copyrighted materials, patentable materials, software, trademarks, and trade secrets, whether or not formal protection is sought.

*Copyrighted Materials* shall include the following: (1) books, journal articles, texts, glossaries, bibliographies, study guides, laboratory manuals, syllabi, tests, case studies, and proposals; (2) lectures, musical or dramatic compositions, unpublished scripts; (3) films, filmstrips, charts, presentations, transparencies, and other visual aids; (4) video and audio CD's, tapes or cassettes; (5) live video and audio broadcasts; (6) programmed instructional materials; (7) mask works; (8) research notes, research data reports, and research notebooks; and (9) other materials or works other than software which qualify for protection under the copyright laws of the United States (see 17 U.S.C. Section 102 et seq.) or other protective statutes whether or not registered thereunder.

*Mask Work* means a series of related images, however fixed or encoded: (i) having or representing the predetermined, three dimensional pattern of metallic, insulating, or semiconductor material present or removed from layers of a semiconductor chip product; and (ii) in which series the relation of the images to one another is that each image has the pattern of the surface of one form of the semiconductor chip product (see 17 U.S.C. Section 901 et seq.).

*Novel Plant Variety* means a novel variety of a sexually reproduced plant (see 7 U.S.C. Section 2321 et seq.).

*Patentable Materials* shall be deemed to refer to items other than software which reasonably

appear to qualify for protection under the patent laws of the United States (see 35 U.S.C. 101 et seq.) or other protective statutes, including Novel Plant Varieties and Patentable Plants, whether or not patentable thereunder.

*Patentable Plant* means an asexually reproduced distinct and new variety of plant (see 35 U.S.C. Section 161).

*Significant Financial Interest* means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). This definition applies equally to the Originator, his or her spouse, or his or her dependent children.

*Software* includes one or more computer programs existing in any form, or any associated operational procedures, manuals or other documentation, whether or not protectable or protected by patent or copyright. The term "computer program" shall mean a set of instructions, statements, or related data that, in actual or modified form, is capable of causing a computer or computer system to perform specified functions.

*Trademarks* shall include all trademarks, service marks, trade names, seals, symbols, designs, slogans, or logotypes developed by or associated with the University System or any of its institutions (see 15 U.S.C. Section 1127).

*Trade Secrets* means information including, but not limited to, technical or nontechnical data, a formula, a pattern, a compilation, a program, a device, a method, a technique, a drawing, a process, financial data, financial plans, product plans, or a list of actual or potential customers or suppliers which: (i) derives economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, other persons who can obtain economic value from its disclosure or use; and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy (see O.C.G.A. Section 10-1-761).