



Institutional Review Board Handbook

Guidelines and Information Related to the
Certification of Research Projects
Connected in Any Manner to Argosy University

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THE AMERICAN PSYCHOLOGICAL ASSOCIATION'S (APA) ETHICAL PRINCIPLES OF PSYCHOLOGISTS AND CODE OF CONDUCT --
HTTP://WWW.APA.ORG/ETHICS/CODE/INDEX.ASPX85
THE BELMONT REPORT -- HTTP://WWW.HHS.GOV/OHRP/HUMANSUBJECTS/GUIDANCE/BELMONT.HTM85

Preface

This Handbook contains descriptions of procedures and forms required by Argosy University for any research project conducted by employees or students of Argosy University, and for the conduct of research by outside organizations or institutions seeking the involvement of any Argosy University employee or student. This includes research done for dissertations, Clinical Research Projects (CRPs), and other significant research, but it also includes research done for student posters, PowerPoint presentations, and class assignments where research is being done. To ensure consistency, this handbook uses the terms *principal investigator* to indicate the person doing the research and *faculty research supervisor* to indicate the principal investigator's dissertation chair, CRP chair, classroom instructor or any other person who is responsible for supervising the research described in the principal investigator's application.

The Institutional Review Board Handbook is organized into four sections.

Section 1: Administration presents the purpose of an IRB, an explanation of its role as the certifier of compliance for the protection of research participants, and the guidelines for operation of an Argosy IRB.

Section 2: Preparation of Applications for IRB Review and Certification of Compliance provides a detailed explanation of the procedures used to prepare and submit an application for certification of compliance.

Section 3: IRB Application Forms and Reports describes the various documents used in IRB certification.

Section 4: Appendixes contains instructions, forms, and links to additional resources.

Applicants should expect to complete an exempt (Appendix A), expedited (Appendix B), or full application (Appendix C), including the appropriate consent form (Appendix D).

The Principal Investigator must also include a completed Conflict of Interest Statement (Appendix P), and CITI completion forms for both applicant and applicant's research chair. The IRB will respond with a Certification Statement or a Letter To Correct IRB Application Deficiencies (Appendix E).

For some research, two or more institutions may be involved; if so, the IRB will send a letter to any other institution which requests Argosy Certification first (Appendix F). If research takes more than one year, the Principal Investigator will fill out a Continuing Certification of Compliance form (Appendix G). When research is completed the Principal Investigator files a Project Completion form (Appendix H).

Research protocols may change, requiring an Amendment to Original IRB Certification form (Appendix I), an Adverse Event Report form (Appendix J), or a Change in Procedure Application form (Appendix K). When a course includes research, faculty must submit an Application for IRB Certification of Faculty Research and Assigned Course Research Projects form (Appendix L), and Assigned Course Research Progress Report (Appendix M).

Annually, each IRB files a Letter of Assurance (Appendix N). Principal Investigators, faculty research supervisors, and IRB Board members must adhere to The American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct; the Code of Federal Regulations; Title 45, Part 46; and the Belmont Report (Resource Links can be found in Appendix Q).

The Compliance Review Procedure in Brief

The Application for Review and Certification of Compliance enables a review of a proposed research study for the purpose of certification of compliance with various governmental and organizational rules and guidelines for the protection of human participants. A critical aspect of compliance is the principal investigator's described understanding of the present and potential feelings of the proposed research participants and the principal investigator's plan to ameliorate any possible adverse reaction to participation. Simply, there are inherent risks associated with any research involving interaction with human participants. It is the principal investigator's responsibility to control to a reasonable extent any potential harm and to have a plan ready to correct any potential harm.

1. The Argosy University Institutional Review Board does not approve research studies but certifies the principal investigator's compliance with guidelines for the ethical treatment of human research participants. The IRB considers the design and data-gathering procedures of the study in its review.
2. Prior to determining level of application and filing the appropriate forms, the principal investigator completes CITI training.
3. The principal investigator, with his or her faculty research supervisor, determines the level of risk to the proposed research study's participants, completes the appropriate Application for IRB Review and Certification of Compliance, and, where needed, provides the appropriate approval documents as attachments. All questions must be answered fully. The faculty research supervisor signs the Application indicating approval that the study has academic merit and meets the requirements for IRB certification.

4. The principal investigator attaches a Conflict of Interest Disclosure Statement (Appendix P) and documentation of principal investigator and faculty research supervisor's CITI completion.
5. The Application is forwarded to the appropriate person (IRB chair, designated person or clerk) for logging and forwarding to the assigned IRB Member.
6. The IRB Member determines the level of the application, reviews it if it is an Exempt or Expedited application, and forwards Full IRB Review applications to the IRB chair for review at the IRB monthly meeting.
7. The cover to the Application for Certification contains certification conditions. A copy of the cover of the application with signatures is returned to the principal investigator, a copy is sent to the faculty research supervisor, and the original Application with the original attachments (with original signatures) and original IRB signatures is placed in an appropriate secure file in campus administrative offices.
8. Upon completion of the study, the principal investigator completes a Project Completion Report form (Appendix A) which is submitted to the college administrative assistant (IRB chair, designated person or clerk) for filing with the principal investigator's original Application for Certification.

Faculty Guidelines for IRB Procedures

1. The principal investigator submits the application for IRB certification to you, the faculty research supervisor, for approval and forwarding to the IRB Chair (or appropriate college administrative assistant, designated person or clerk) for logging in. The IRB Chair forwards the petition to the designated IRB member. Please be aware that this applies to any research that contributes to generalizable knowledge. This includes, but is not limited to, research that contributes to generalizable knowledge for dissertation, CRPs, class assignments, surveys, and conference presentations and posters.
2. Review the Informed Consent documents. Make sure that all the elements of informed consent are included. Especially check to make sure that the strictly voluntary participation statement follows the model.
3. Be sure all the forms are completed and signed by both you and the student. A conflict of Interest Statement, the student's CITI completion form and your CITI completion form must be attached.
4. Please review the completed Application Form Checklist and make sure that all required documents are included in the application packet. Please initial that the packet is complete.
5. The IRB generally has up to 30 days (Exempt and Expedited) and 60 days (Full IRB Review) to make a decision. However, your IRB member or college representative will make every reasonable effort to complete the process in the shortest time possible. Forms completed in a haphazard manner or that are missing information will necessarily take longer than 30 or 60 days.

Your IRB member or college representative may return forms that are improperly completed (for example, a form in which an answer is "See

attached” and the attached document is the student’s proposal). Regarding the above time limits, the clock starts upon receipt of a *completed* application.

6. Also, carefully note the plan for confidentiality of participant information. This must include a plan for collection, storage, and (eventual) disposal of the data. Studies are confidential or anonymous: they cannot be both.
7. Most studies entail some risk. When reviewing this section, consider the worst-case scenario (including psychological distress). The application must consider this and include a plan for intervening in a responsible and helpful manner.
8. Encourage students to communicate with you, the faculty research supervisor, regarding IRB questions. Feel free to ask your IRB representative if you (or the student) have questions. Please do not refer students directly to IRB members.

DATA COLLECTION CANNOT BEGIN UNTIL IRB CERTIFICATION IS OBTAINED.

If a principal investigator has violated this Federal requirement, he or she may be required to start over. There may be other consequences as well (up to and including dismissal from the university). There are no exceptions. Any violations of this policy must be reported to the IRB chair.

9. Changes in procedure, committee, etc., require re-certification. Changes in procedure require that data collection cannot begin until the resubmitted application is Certified. Typically, change in procedure paperwork can be reviewed and Certified quickly.

10. Certification is for one year. If the project extends beyond that time, the principal investigator must apply for an extension.
11. Any and all IRB questions, problems, violations, etc., should be referred to the IRB member for discussion.
12. Please note that the IRB will not accept hand-written applications or applications submitted on previous versions of the IRB forms. The applications in this document are templates and information can be typed in without affecting the form. Information from the research proposal may be used. **Including references to a proposal or pasting in closely related materials instead of answering the questions is not acceptable.**

SECTION 1: ADMINISTRATIVE DOCUMENTS

Responsibilities of National and Local Campus Institutional Review Boards

Argosy University's Institutional Review Boards certify compliance with research guidelines that provide for the ethical treatment of human research participants. The Institutional Review Board carries out its primary responsibility by reviewing applications for certification of compliance submitted by principal investigators.

Argosy University has two kinds of Institutional Review Boards (IRB): the National Review Board, which reviews proposals of research projects to be conducted at the national level or where two or more Argosy campus sites are involved, and Campus review boards, which review proposals of research projects to be conducted at the single campus level.

The National IRB is comprised of the chairs of the campus IRBs. The National IRB is tasked with reviewing national research projects, ensuring consistent application of the guidelines contained in this manual, reviewing and updating the IRB Handbook, assisting campus IRBs in implementing the IRB Handbook guidelines, providing guidance to local IRBs, when asked, and facilitating the interaction of the various local IRBs via a listserve, teleconferences and other methods.

Campus IRBs review all research conducted by anyone in any way affiliated with the campus. To carry out their work, the campus IRBs establish their own calendar and procedures for the review of applications for certification of compliance as described in this handbook. The campus IRB announces its responsibilities and holds meetings to train principal investigators and their supervisors in the processes and procedures for review of campus research projects.

While the operation of a local IRB is subject to monitoring by the national IRB, for application review decisions an IRB is autonomous, and the decisions of the local IRB and the National IRB are not subject to review or appeal.

Annually, each IRB files a Letter of Assurance with the unit's chief academic officer, indicating that the IRB is duly constituted according to the following guidelines and that it will conduct its reviews in accordance with the guidelines. A copy of the campus Letter of Assurance is also sent to the chair of the National IRB.

The following describes the mission, guiding principles, and procedures for both boards.

Mission and Guiding Principles

Mission

The mission of the Argosy University IRB at each campus, and at the national level, is to ensure the ethical treatment of human participants in the conduct of any and all research by any individual affiliated with Argosy University, in accordance with the guidelines set forth in the Code of Federal Regulations and the Belmont Report. The IRB does not approve research projects, but certifies that the protection of research participants has been adequately provided for as described in an Application for IRB Review and Certification of Compliance. The principal investigator and the investigator's faculty research supervisor are responsible for seeing that the procedures for the protection of human participants are carried out as described in the application for certification.

IRB Certification of Compliance

Each principal investigator proposing a research project large or small must request IRB review and Certification that the proposed research project complies with the guidelines set forth below for the protection of human participants. This policy applies, regardless of source of funding and location of study, to all research studies or pilot studies conducted by or on faculty, staff, students, or employees of Argosy University, or by or on Argosy University as an institution. This policy applies to research being done in preparation for conference presentations or posters as well.

A review of a research project by the IRB is initiated with an Application for Certification (Appendixes A, B, & C) and is concluded by a Completion of Research Form (Appendix H)

Review of Applications for Certification

Applications for certification involving university-wide research that come from non-Argosy investigators are reviewed by the National IRB. Research involving studies that originate with an investigator on an Argosy campus and concern a single campus are reviewed by the campus IRB. Campus IRBs also review research involving non-Argosy investigation that will be

conducted locally. At the national level, or when more than one campus site is involved, the National IRB chair will form an ad hoc IRB subcommittee consisting of 2-3 campus IRB chairs to review the certification request. In most cases, the subcommittee will include the IRB chairs from the sites where the proposed research will take place. The review procedure is the same as for campus IRBs. Records of the action of the university-wide IRB will be kept on the IRB SharePoint and reported in the minutes of the IRB chairs' meetings.

The principal investigator, after completing CITI training and in consultation with his or her faculty research supervisor, submits an appropriate level of an Application for Certification: Exempt (Level 1), Expedited (Level 2) or Full IRB Review (Level 3), based on an assessed risk-to-benefit ratio.

In brief, *Exempt* is generally reserved for studies that use archived data or literature reviews, and for which there is no principal investigator-participant interaction. The *Expedited* application is used for those studies with low-to-moderate risk to the participants, which can be reduced through the protection-of-participants' procedures planned by the principal investigator. The *Full IRB Review* application is used in those instances where the principal investigator is working with a protected class of participants or the risk-to-benefit ratio is high.

The review of an *Application for IRB Review and Certification of Compliance* may result in one of these three outcomes:

1. "Certified" – Certified as written with no conditions (signed cover);
2. "Contingently Certified" – The research application or the procedures for the protection of the research participants described in the application are deficient in one or more minor areas. A memorandum (Appendix E) is attached to the application that specifies deficiencies or changes that must be completed and documented prior to beginning the research (For these deficiencies, the IRB Chair or designated reviewer can, upon reviewing the Principal Investigator's response(s) to the required changes, certify the research proposal on behalf of the IRB.
3. "Not Certified" – The research application or the procedures for the protection of the research participants described in the application are significantly deficient in one or more areas (unsigned). A memorandum (Appendix E) is attached to the application that specifies deficiencies or changes that must be completed and documented prior to beginning the research (For these deficiencies, the IRB Chair or designated reviewer

can, upon reviewing the Principal Investigator's response(s) to the required changes, certify the research proposal on behalf of the IRB.

Whether the Application for Certification of Compliance is submitted before or after a dissertation proposal defense is a campus decision. No research may be conducted for any Argosy University-related research project without prior certification by the appropriate IRB.

Appeal of IRB Decision

If a principal investigator wishes to contest an IRB decision, he or she may ask the IRB to reconsider. No further appeal is possible. No faculty member or administrator may conduct or approve a research project involving human participants that has not been certified by the IRB to be in conformance with applicable ethical and legal standards.

Definitions

Argosy University uses the following definitions of terms as adapted from the *Code of Federal Regulations (CFR Title 45, Part 46, 1991* and the Belmont Report.

Human Participant means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual. (Following the position of the American Psychological Association, Argosy University uses the term *participant* in place of the term *subject*.)

Intervention includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes.

IRB Certification means the determination of the IRB that the research (project or activity involving human participants) has been reviewed and may be conducted at an institution within the constraints (guidelines) set forth by the IRB and by other institutional (including employer) and federal regulations.

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

This definition sets the baseline used to establish the three levels of risk used by Argosy University IRBs to establish IRB review guidelines for the certification of compliance.

Research (project, study, protocol, etc.) means a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to knowledge. This term may include dissertations, CRPs, some classroom projects, and research conducted in preparation for a conference presentation or a conference poster.

Guiding Principles

The purpose of an IRB review is to determine whether participants in a research study will be placed at physical or mental risk and, if risk is involved, to certify that the following conditions have been met:

1. Risks to participants are minimized. This is an essential condition for certification. The determination of when a research participant is at risk is a matter of the application of common sense and sound professional judgment as it relates to the circumstances of the research activity in question. The IRB will carefully weigh the relative risks and benefits of the research procedures as they relate to the participants.
2. Participants in the study (and their guardians) are fully aware of the risks and that individuals may withdraw from the study at any time without any form of penalty.
3. Research activities, designed to yield fruitful results for the benefit of individual participants or society in general, may incur risks to the participants provided such risks are outweighed by the benefit to be derived from those activities.
4. Risks to the participants are so outweighed by the sum of the benefits to the participants and the importance of the knowledge to be gained as to warrant a decision to allow the participants to voluntarily accept these risks.
5. The degree of risk involved in any activity should never exceed the humanitarian importance of the problems to be solved by that activity. Likewise, compensation to volunteers should never be such as to constitute an undue inducement to the participants.
6. Rights and welfare of any such participants will be adequately protected. There is a wide range of medical, social and behavioral research projects and activities in which no immediate physical or mental risk to the participant is involved, for example, those utilizing

personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, or stored data. Some of these procedures, however, may involve varying degrees of discomfort, harassment, or invasion of privacy, which may constitute a risk.

Some studies depend upon stored data or information that may have been obtained for quite different purposes. Here, the IRB will determine whether the use of these materials is within the scope of the original consent and whether new consent should be obtained or whether consent is waived. The IRB may ask to see the original consent in order to make this determination.

Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this document.

Conduct of the research activities may be reviewed at intervals determined by the IRB, but not less than annually.

IRB Certification is for one year and is terminated by a Report of Completion of a Research Project. Certification is automatically terminated at the end of one year and may be extended by a Request to Extend Certification signed by the principal investigator and the faculty research supervisor.

Code of Federal Regulations

Argosy University IRBs adopt, as part of their guiding principles, the *Code of Federal Regulations*. These regulations are adopted in their most current version. If disagreements arise between the Argosy University IRB policies and procedures and the Title 45 of the Code of Federal Regulations, the latter has preeminence.

Ethical Principles

Argosy University IRBs adopt, as part of their guiding principles, the Ethical Principles for the protection of human research participants as published in the *Belmont Report* and other documents.

A Cautious Stance

Argosy University IRBs will err on the side of caution in ensuring the protection of research participants.

Membership and Governance of the IRB

Membership

Each campus IRB shall have at least five members, with varying backgrounds, who will review research activities commonly conducted by the institution. The IRB shall be sufficiently qualified, through the experience, expertise, and diversity of the members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. The composition of the IRB should reflect the university's commitment to diversity.

Campuses may use a variety of procedures to identify members of the campus IRB. The IRB is responsible for perpetuating itself within the guidelines of the Handbook. The board may invite new members, and colleges or departments may designate a representative (who as a designee of the chairperson) who will review the applications of that college. The chairperson may solicit participation with an eye to the guidelines in the paragraph above. New campuses may initiate an IRB by appointing a temporary IRB chairperson.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to certify the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

At least one of the members present must have no affiliation with Argosy University other than serving on the IRB. The IRB shall include at least one member whose primary concerns are in scientific areas. At least one member present must have as his or her main interest non-scientific issues.

Every effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB based on gender.

No IRB may consist entirely of members of one profession. All colleges and schools in the university campus should be represented on each IRB.

The National IRB is composed of chairpersons of campus IRBs, reflecting the diversity described above.

Exceptions to these rules must be requested by the campus IRB chairperson, approved by the Argosy University Vice President of Academic Affairs, and noted in written correspondence to be maintained by the campus IRB.

IRB Governance

Links to pertinent federal law related to Governance are found in Appendix Q “Governance Guidelines.”

Self-governing. Each IRB is self-governing. No other group or individual may interfere with its decision-making process or overrule its decisions. Policies and procedures governing Argosy University IRBs may be changed only by the university-wide National IRB, except for procedural details unique to each campus, which may be changed by the IRB of that campus at a regular meeting and approved by the national Vice-president of Academic Affairs.

Role of IRB Chairperson. Each IRB shall designate a chairperson using a process to be determined by each campus. With the approval of the full IRB, the chairperson shall

1. Conduct the meetings of the IRB;
2. Assign certification authority to the members;
3. Maintain a record of the proceedings of the IRB meetings, including agendas, actions of the IRB and the certification logs of the members; and
4. Maintain a record of all IRB members for that campus, including current curriculum vitae for each member.
5. Invite new board members.

Authority. Unless otherwise agreed upon, the full IRB retains authority over all matters related to its responsibility to assure the protection of research participants.

Membership of National IRB. The membership of the National IRB will reflect the above guidelines but be composed of campus IRB chairpersons.

Meetings of the Institutional Review Board

Meeting schedule. The IRB shall establish a calendar of full Board meetings appropriate to the campus and university calendar. The IRB must schedule sufficient meetings to conduct its business in a timely manner.

Yearly organizational meeting. Each IRB must conduct an annual organizational meeting at which time the members of the IRB agree to comply with the guidelines and procedures established for the IRB and sign a Letter of Assurance to be submitted to the unit's chief academic officer.

On the occasion of its annual organizational meeting, each campus IRB shall constitute itself for the current academic year. The IRB will, at its constitutional meeting,

1. Admit new members and dismiss members who wish to terminate their service on the IRB;
2. Select a chairperson from among its membership as per campus protocols;
3. Review applicable parts of *Title 45 of the Code of Federal Regulations*, ethical guidelines published in the *Belmont Report*, and other applicable state and federal laws, rules, and regulations to determine what, if any, changes have been made in these rules and regulations;
4. Direct all new members to complete the training program for new IRB members (The Argosy IRB SharePoint has information about available training opportunities);
5. Establish a schedule of meetings for the current academic term to be made available to the campus (If the schedule changes from term to term at a campus, the schedule for each term shall be made available to the campus at the beginning of each term).

The chairperson also authorizes specific members to review assigned Applications for Certification, and further authorizes the members to determine and Certify Exempt and Expedited Applications, and to prepare and place on the full IRB agenda requested Full IRB Review (Level 3) Applications and other applications the member determines may require full Board review.

Letter of Assurance. At the conclusion of the annual organizational meeting, each IRB shall prepare and file with the chief academic officer for that unit, a Letter of Assurance which states the composition of the IRB (the names, positions and affiliations of its members), its proposed meeting schedule, and its agreement to abide by the guidelines set forth in this document. Any changes in any of the elements of the Letter of Assurance shall be reported in a subsequent letter.

Regular meetings of the full Institutional Review Board. While a set monthly meeting date is desirable, the IRB shall establish a calendar of full Board meetings appropriate to the campus and university calendar. The IRB must schedule sufficient meetings to conduct its business in a timely manner.

The primary purpose of these monthly meetings is to review Full IRB Review (Level 3) Applications for Certification. While Exempt and Expedited applications may be reviewed by the IRB Chairperson, or the Chairperson's designee on a continuous basis, Full IRB Review applications must be reviewed by the full IRB, at their scheduled monthly meetings.

Designated reviewers present logging reports of Exempt and Expedited Applications to the full IRB at their scheduled monthly meetings.

The board also conducts any other business of the IRB. The IRB follows Robert's Rules of Order (Robert et al., 1984) in all its procedures and meetings.

Quorum. A majority of members of record shall constitute a quorum for the purposes of conducting the business of the full IRB. A quorum of members (>50 %) is required at full Board meetings, and lack of a quorum prohibits convening the meeting.

At the beginning of each full Board meeting, members should certify for the record that they have no conflicts of interest in any research project currently under consideration. If any member who is a co-investigator, or otherwise has a conflict of interest with a research project, he or she must be excused from voting.

Special attention must be paid to ensure that a quorum is not lost during a meeting. If a member abstains from voting, or is excused due to a conflict of interest, a quorum of total members must still remain. If not, the research project in question cannot be certified. Also, if during the meeting, the number of members present falls to a level below that required for a quorum, the meeting must be adjourned.

Consultation

If the IRB determines it may lack expertise in an area of research that is the subject of a research project submitted for IRB certification, the IRB may, at its discretion, either during a scheduled meeting or outside scheduled meetings, include outside consultants in its deliberations. Consultants may not vote on the submission under consideration.

Conflict of Interest

A member of the IRB may not certify compliance of a research proposal for which the IRB member has a direct interest either as (a) an investigator, or (b) as a committee member or faculty sponsor of a student's project. (Appendix P)

Record of IRB Actions and Activities

Required records. Records of all business conducted at monthly meetings of the IRB shall be kept in a safe location by the chairperson. Records shall include agendas and minutes of the business meetings. Records of IRB applications shall be managed through the logging procedure described below. In addition, copies of the IRB applications shall be kept in the investigator's academic file or, for principal investigators who are not students, in a separate file controlled by the IRB chairperson. Annual reports from the campus IRBs will be submitted to the campus president or designee.

Tracking procedures and submission procedures. Each IRB shall develop a logging-tracking procedure (Appendix O) which accounts for each application from the beginning to the end of the review process.

The principal investigator, in consultation with his or her faculty research supervisor, prepares, and signs an application for certification of compliance appropriate for the procedures of the study.

The faculty research supervisor reviews the principal investigator's application and, if appropriate signs his or her approval and forwards the application to the designated clerk who records (logs) the receipt of the application and records the forwarding of the application to the designated IRB member.

The IRB member reviews the application and determines if the correct level of application has been presented. If the application level is correct, the IRB member reviews and certifies Exempt and Expedited applications. If the application is a Full IRB Review (Level 3), the member requests in writing that the IRB Chairperson place the Level 3 Application on the agenda of the next available monthly meeting. The member also duplicates and distributes copies of the Level 3 application to all IRB members before the meeting with a cover note requesting their review.

If the IRB member determines that the level of application is completed incorrectly, the member returns the application with a Letter to Correct IRB Application Deficiencies (Appendix E) requesting the application be completed correctly to the clerk for logging and subsequent return to the faculty research supervisor. The faculty research supervisor may forward the application to the principal investigator for correction or hold the application and request that the investigator supply missing components.

Once an application has been certified, the clerk copies the application cover page and makes a copy of the complete application to return to the faculty research supervisor with the original copy returned to the principal investigator. The copy of the cover with signatures is filed in the principal investigator's permanent file, if the principal investigator is a student, or into a designated, secure file if the principal investigator is not a student.

A copy of each month's application transactions copied from the clerk's log is submitted to the IRB chairperson as part of the monthly IRB meeting. If the logging procedure is electronic, appropriate conveyance procedures are developed by the IRB.

IRB Compliance Audits

Investigating noncompliance. Any reported significant deviation in activities previously certified by the IRB must be investigated by the IRB as an issue of noncompliance with certification requirements. An *ad hoc* subcommittee of the IRB composed of the Chair and any other IRB member whose presence is deemed as essential will be appointed by the Chair.

Reporting an issue of noncompliance to the IRB. The Chair shall brief the IRB, at the next scheduled meeting or at a specially convened meeting, on the details of an allegation of noncompliance by a principal investigator. The IRB will then determine if there was, in fact, a violation of regulatory or institutional policies. If a violation occurred, the IRB will then determine what restrictions, conditions, or other actions are necessary to resolve the non-compliance, and what procedures will be required to prevent future occurrences.

The principal investigator will then be notified in writing of the requirements or conditions necessary to ensure compliance with the restrictions, conditions, or decisions of the IRB. Every effort will be taken to ensure the confidentiality of all aspects of the investigation and any subsequent IRB actions relating to the incident(s). In the case of student investigators, a referral to the Ethics and Evaluation (Student Conduct) Committee may be made.

When appropriate, University administrators (deans and department heads) will be informed.

SECTION 2: PREPARATION OF APPLICATIONS FOR IRB REVIEW AND CERTIFICATION OF COMPLIANCE

Purpose of Review

The purpose of IRB review of a proposed research project is to certify compliance with Argosy University research standards for the protection of the rights and welfare of participants in research projects. To this end, the background, purpose, and methodology of proposed studies are reviewed to determine any potential physical, psychological, social, and legal risks to the proposed research participants, the protection of their confidentiality and the adequacy of their informed consent. All principal investigators must follow the guidelines for collaboration with participants and other stakeholders as noted in the *Publication Manual of the American Psychological Association* (6th ed.); the *Belmont Report* and *APA Code of Conduct* (Appendix Q).

The Board does not ordinarily review scientific design, but may do so if the design of the study could affect the risk-benefit ratio.

Criteria for IRB Certification of Research Projects

In order to certify compliance with Argosy University research standards for the protection of participants, the appropriate IRB shall determine that all the following requirements are satisfied.

Risks to participants are minimized

Adequate provisions are described to protect the privacy of participants and to maintain the confidentiality of data; procedures are used which are consistent with sound research design and which do not unnecessarily expose participants to risk; and whenever appropriate, procedures are already being performed on the participants for diagnostic or treatment purposes.

Risks to Participants are Reasonable

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

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

Selection of Participants is Equitable

In making this assessment, the IRB takes into account the purposes of the research and the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations when some or all of the participants are likely to be vulnerable to coercion or undue influence. Vulnerable populations include children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Additional safeguards are required in the study to protect the rights and welfare of these participants.

Informed consent will be sought from each prospective participant, or the participant's legally authorized representative, in accordance with, and to the extent required by, federal guidelines. Informed consent will be appropriately documented, in accordance with, and to the extent required by, federal guidelines.

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

Participant selection must be appropriately reviewed by the principal investigator and the faculty research supervisor, as well as the principal investigator's institutional review board or designated authorizer prior to submission for Argosy University IRB review.

Benefits of Review

IRB review offers the following benefits to investigators and the institution:

1. It certifies that the investigator's research project is in compliance with ethical guidelines and with state and federal rules and regulations;

2. It may bring to the attention of an investigator ethical factors which may not have been considered; and
3. It demonstrates and documents the institution's commitment to the protection and ethical treatment of human participants.

Definition of Human Research

For purposes of defining the purview of campus IRBs, human research is any activity with the primary intent of securing information from or about human participants for the purpose of advancing basic, clinical, or psychosocial understanding of humans. Such activity may or may not differ significantly from psychological or other professional practice. Such research includes, but is not limited to, the following: group design studies, classroom projects, single participant design studies, case reports and analyses, chart review, observational studies, paper and pencil based studies, qualitative studies, research in preparation for a conference presentation or poster, or comparison of interventions. This includes pilot studies with small samples. Internal research conducted at Argosy for purposes such as program review, departmental assessment and university accreditation do not require IRB review.

Studies Requiring Review

To ensure the protection and ethical treatment of human participants, and to comply with federal and state laws, Argosy University requires that, prior to their initiation, all research projects, except for those conducted internally by Argosy for self review, be reviewed and a determination of compliance be made by the Argosy University IRB.

Categories of Certification

There are three levels of Certification: *Exempt (Level 1)*, *Expedited (Level 2)*, and *Full IRB Review (Level 3)*, based on risk/benefit ratio to the participants. The investigator must assess the level of risk, or exposure to sensitive or harmful experiences, due to participation in the study and assign a level status to the application (see Section 3).

The IRB determines the certification level of a research project.

Studies Qualifying for Exempt Review (Level 1)

Argosy University reserves the Exempt (Level 1) application for research projects using archived data and research projects for which there is no human participant interaction, such as a literature review. Thirty days may be required for processing after receipt of a complete application. One IRB member's (the Argosy campus school representative or the IRB Chair) signature is required.

Sensitive topics and vulnerable participants, such as children or minors, pregnant women and prisoners, do not qualify for exempt research. International studies also do not qualify for exempt IRB review.

The IRB makes the final determination about whether a proposal is Exempt.

Studies Subject to Expedited Review (Level 2)

The Expedited review process is used to review certain categories of research, involving no more than moderate risk to human participants. Any research in which human participant interaction is anticipated falls in this level unless risk to participants is more than moderate. Most studies will fall into this level. Thirty days may be required for processing after receipt of a complete application. One IRB member's (the designated IRB member or the IRB Chair) signature is required.

In addition to meeting the general eligibility criteria described previously, the research must also meet the Certification criteria as follows:

1. The risks to participants for participating in the research must be reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be gained.
2. Participant selection must be fair.
3. Informed consent will be sought and documented unless a waiver of consent or documentation of consent has met the waiver criteria.

4. The plan to collect and monitor data assures participant safety.
5. Procedures provide for the privacy of participants and for maintenance and disposal of confidential data.
6. Where necessary, additional safeguards are included to protect vulnerable participants.

Studies Subject to Full IRB Review (Level 3)

Research projects that entail sensitive or risky research topics or methodologies require Full IRB review in a full Board meeting. These applications must contain extensive detail describing procedures designed to protect vulnerable participants. A majority of IRB members must approve the proposal and sign the cover page. Sixty days may be required for processing after receipt of a complete application.

Procedures for Applying for Certification of Compliance

BEFORE ANY DATA ARE GATHERED, THE INVESTIGATOR MUST OBTAIN A CERTIFICATION OF COMPLIANCE. FAILURE TO FOLLOW THIS GUIDANCE IS A VIOLATION OF FEDERAL LAW AND ARGOSY UNIVERSITY POLICY. IT MAY RESULT IN THE INVESTIGATOR'S RESEARCH BEING DISQUALIFIED, AND IT MAY RESULT IN OTHER DISCIPLINARY CONSEQUENCES, UP TO AND INCLUDING DISMISSAL FROM THE UNIVERSITY.

In brief, after completing CITI training the principal investigator, in consultation with his or her faculty research supervisor, prepares and signs an application for certification of compliance appropriate for the procedures of the study. Attached to the application are (a) proposed Letters of Consent, (b) interview and survey questions to be used in the study, (c) appropriate institutional approval letters, (d) a conflict of interest form, and (e) both principal investigator and faculty research supervisor's CITI completion forms as noted in the application.

STEP 1: Initial Review

For a research project conducted as part of a student's academic work, the following applies: At least one member of the Argosy University core faculty (serving as faculty research supervisor or dissertation chair) will evaluate whether the project has scientific merit and whether the research project conforms to IRB submission guidelines. Upon determining that the project has both merit and has been prepared according to guidelines, the faculty member will sign the cover sheet that is part of each set of forms.

For other research projects, the principal investigator's faculty research supervisor conducts a similar review and signs the cover sheet.

STEP 2: Logging the Application.

The faculty research supervisor forwards the application to the designated clerk (or person designated for this procedure) who logs the application and forwards the application to the designated IRB member. *Faculty research supervisors are encouraged to use the IRB application checklist as a cover to the application as a device for assuring the completeness of the application.*

STEP 3: Review by Designated IRB Member.

The designated IRB member reviews the application and determines if the level of the presented application is correct. If the application level is correct, the IRB member reviews and certifies Exempt (Level 1) and Expedited (Level 2) applications. If the application is a Full IRB Review (Level 3), the member requests in writing that the IRB Chairperson place the Level 3 application on the agenda of the next available monthly meeting. The member also duplicates and distributes copies of the Level 3 application to all IRB members.

STEP 4: Certification or Resubmission.

If the IRB member determines that the information on the application is not correct or is incomplete, the member returns the application with a note requesting correction of deficiencies to the clerk for logging and subsequent return to the faculty research supervisor for the principal investigator to fix. The faculty research supervisor returns the corrected application to the clerk for logging and forwarding to the IRB member with the original note describing any deficiencies.

STEP 5: Filing of Application.

The cover to the Application for Certification (Appendix A, B, or C) contains certification conditions. A copy of the cover of the application with signatures is returned to the principal investigator, a copy is sent to the faculty research supervisor, and the original Application (Appendix A, B, or C) with the original attachments (with original signatures) and original IRB signatures is placed in an appropriate and secure file in campus administrative offices.

STEP 6: Project Completion Report.

The last step in the IRB review process is completion of the IRB Project Completion Report (Appendix H) which is submitted by the investigator at the conclusion of the research project as part of the final research requirements *in accordance with Federal Regulations*. The form is completed after the final defense and is submitted as part of the final defense paperwork.

For other research activities, it is submitted at the conclusion of the research project. Submission is the responsibility of the principal investigator and faculty research supervisor.

The Project Completion Report is filed with the principal investigator's original application.

Informed Consent

Consent process

Ethical practice and law require that a participant's consent be intelligent, knowing, and voluntary. It is essential that consent to participate in a research project be obtained under circumstances where a participant has (a) reasonable time to listen to investigators' explanations and (b) the participant's physical, mental, or psychological state does not impede comprehension of information or the ability to make rational and non-coerced choices. To ensure the validity of consent where other than minimal risks are involved, the initial presentation to the participant should precede execution of the consent form by several hours or days. In addition, investigators should try to avoid using participants whose capacity for competence to give consent is limited because of mental infirmity, medication, severe debilitation, pain, etc. Such participants should be thought of as non-consenting.

Most persons under the age of 18, or persons judged legally incompetent due to mental disability, are legally incapable of consent and their legal guardians must be petitioned for permission or consent on their behalf.

Investigators must also allow a minor or legally incompetent participant the right to refuse to participate in the study even if guardian approval has been secured. In studies involving minors, the children must be permitted to agree or refuse to participate in the research project. Investigators must obtain and document the assent of minors and legally incompetent persons to participate in the research project. Adults cannot sign away the rights of children to choose their participation in research projects.

Consent form

The documented consent form is a statement that gives potential participants sufficient detailed information about the study, and sufficient opportunity to read and review the consent

form, to allow meaningful decisions about participation. A model consent form and an alternate consent form can be reviewed in Appendix D.

Elements of Informed Consent

Except as described here, investigators may not enroll human participants in research unless they have obtained the legally effective, written, informed consent of the participant or the participant's legally authorized representative prior to enrollment of the participant in the research.

This holds true for studies using internet surveys and other electronic data-gathering devices. The approval of the principal investigator's committee is required for procedures used to gain participant approval. In studies using internet technology, for example, a letter of consent, which has an embedded link to a survey, may contain a statement that by answering the survey the invited participant agrees to the conditions described in the letter of consent, including voluntariness and use of the data.

Investigators are responsible for ensuring that participants, or their representatives, are given sufficient opportunity to consider whether to participate and must seek to avoid coercion or undue influence. Information given to potential participants or their representatives must be in language that is understandable to the participant or participant's representative. No process of obtaining consent may include exculpatory language through which the participant waives any of their legal rights or releases or appears to release the investigator, sponsor, or institution or its agents from liability for negligence. The IRB, at its discretion to comply with changing requirements, has the authority to alter these requirements or waive the informed consent process.

Appendix D contains a detailed explanation of factors, including formatting of the consent form, which must be considered in the creation of an appropriate consent form. The principal investigator should review these statements even if the principal investigator chooses to use the model consent paragraphs.

Special Consent Procedures

Oral Consent

In most cases, a written consent is required. However, on rare occasions oral consent may be considered more appropriate. For such studies, the investigator must submit in writing to the IRB the information that is to be presented to participants orally, an explanation of why oral consent is considered more appropriate, and a request for a waiver of the requirement for written consent.

Internet Consent

Internet surveys require participant consent (see elements of consent) which may be gained with a descriptive paragraph that contains words to the effect that by taking the online survey the participant is giving approval. The request's cover letter should contain all elements of a formal informed consent document, and should conclude with wording such as, "I have read the cover email/letter detailing the purpose and procedures for this research, and I am completing this survey as evidence of my consent to be a participant in this research project."

Waiver of Informed Consent

The IRB may waive the requirements for obtaining informed consent, or certify a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed previously, provided that

1. the research involves no more than minimal risk to the participants;
2. the waiver or alteration will not adversely affect the rights and welfare of the participants;
3. the research could not practicably be carried out without the waiver or alteration, and, whenever appropriate, the participants will be provided with additional pertinent information after participation; and
4. if the informed consent is waived, the conditions of the waiver must appear in the minutes of the meeting in which the waiver is approved.

Documentation of Informed Consent

Proposed Informed consent documents are reviewed as part of the IRB certification process. Signed consent forms are maintained by the principal investigator and disposed of at the conclusion of the research project as part of the maintenance of confidentiality of the research participants.

The participant or the participant's guardian must sign the consent form before the research is conducted. It is assumed that the consent form is only part of the total consent process in which the investigator, perhaps using the written consent form as an outline, describes all facets of the study and answers the participant's questions. The investigator is responsible for ensuring that research participants understand the research procedures and risks. Failure of the participants to ask questions should not be construed as understanding on the part of the participant.

Conflict of Interest

An investigator may have a conflict of interest when other interests, such as financial or other personal gain or personal relationships, bias his or her judgment regarding the welfare of study participants or the integrity of the research. Investigators must disclose any conflicts of interest to the IRB, study participants, and in any publications resulting from such research. The IRB will review the potential conflict and determine if the investigator has minimized the risks involved and provided for the disclosure of such information to the participants. Conflicts of interest can be reviewed as a research risk.

A Conflict of Interest statement (Appendix P) must be submitted with all IRB applications. This disclosure must be updated annually, as the IRB research project is renewed or amended. It is required that all investigators comply with the conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential conflicts of interest or the principal investigator is in jeopardy of forfeiting IRB Certification. Principal investigators may use the model statement in Appendix P.

Collaborative Institutional Training Initiative (CITI)

The Collaborative Institutional Training Initiative (CITI) Program is a subscription service that supports research ethics education. Argosy subscribes to CITI in order to promote

the highest ethical standards for research reviewed by its Institutional Review Boards. Prior to applying for IRB certification, each principal investigator must complete the required CITI modules and document completion as part of his or her application. Additionally, each IRB application must contain documentation of completion by the principal investigator's faculty research supervisor. The training must be renewed at 5 year intervals (see link in Appendix Q).

Research Conducted at the Place of Employment

Proposals to conduct research at the principal investigator's place of employment are carefully reviewed because of the risk of a dual relationship that the principal investigator may have with the research participants; that is, there may be perceived bias or perceived coercion to participate by the participants in these studies. In writing their proposals, principal investigators must clearly address any conflict of interest that such studies can present. Investigators are strongly urged to avoid the use of participant pools of convenience. See section titled Conflict of Interest. Internal research conducted at Argosy for purposes such as program review, departmental assessment and university accreditation do not require IRB review.

Class Research Projects

Research conducted by students, as part of their class work, and class research conducted by professors, as they work with students, is subject to IRB Certification. (Appendix L).

To judge whether any particular classroom assignment needs IRB certification, faculty must consider the nature of the assignment. In-class or out-of-class informal interviews, used for class purposes typically do not need IRB review. These assignments are not research *per se*, because their focus is on informational interviewing rather than collecting data for a research project that may lead to publication or to a public presentation. However, if these out-of-class assignments involve sensitive topics, proprietary information, or vulnerable or special populations, and taping or participant identification is possible, then IRB certification is needed.

Research at Argosy University must meet the highest professional and ethical standards. Activities designed to train students in research methods in the normal classroom setting usually do not fall within the federal definition of research. However, any research conducted with the

intent to either contribute to generalizable knowledge or to construct knowledge related to a specific situation that will be published or presented within an academic discipline, even that originating from the classroom activity, falls within the requirement for IRB review.

Undergraduate or graduate student research activities that reach outside of the classroom may fall under the federal definition of research depending upon the type of interaction with the research participant(s) and the risk involved. Research (see below) completed in preparation for a conference presentation or poster requires IRB review. Graduate theses and dissertations are clearly understood as research, and fall within the IRB purview when human participants are involved. When in doubt, faculty research supervisors should consult with their local IRB board to ensure compliance.

The faculty instructor has the responsibility for ensuring that the student is educated on the general principles of research ethics, human participant protection, and investigator training. To provide guidance to faculty members, the IRB has developed the following criteria to determine if classroom assignments require IRB Certification:

1. Are the participants from a special population such as minors (under 18 years old), prisoners, patients, physically or mentally challenged individuals, or pregnant women?
2. Does the assignment require using a setting such as prisons, nursing homes, hospitals, or schools?
3. Does the assignment focus on topics such as alcohol or drugs, depression or suicide, learning disabilities, abortion or AIDS or HIV or sex, sexually transmitted diseases, eating disorders, or psychological inventories?
4. Does the assignment include audio taping or videotaping?
5. Will participants be directly identified through the assignment?
6. Will the data be formally presented to any audience outside of the class?
7. Will the research extend beyond the realm of the classroom environment?
8. Does the assignment require the use of proprietary or privileged information that is not publicly available?

If the answer to any of the above questions is yes, the project must be reviewed by the IRB. Faculty and students may contact the IRB to discuss the assignment and obtain assistance in determining if review is needed.

Research projects Lacking Definite Plans for Human Participant Involvement

Certain types of activities are planned and initiated with the knowledge that human participants will be involved, without definite plans for their involvement. Examples of such proposed activities are

1. Training programs in which individual training projects remain to be selected and designed;
2. Research, pilot, or developmental studies in which the involvement of human participants depends on such things as the completion of survey instruments or prior studies that have already been certified to conform; and
3. General support programs where selection of the project is the responsibility of the institution or program administrator. In consultation with the investigator's supervisor, the appropriate anticipated level of review application is to be submitted to the IRB with as much information as is available. The application must include assurances that additional information will be submitted when developed, and in the case of training grants, that all trainees will submit individual applications if human participants are to be used.

Cooperative Research Activities

The Institutional Review Board has special requirements for the review and Certification of proposals involving cooperative activities. Cooperative activities are those in which AU faculty, staff, employees or students, seek access to human participants at one or more cooperating institutions, or when investigators from cooperating institutions seek access to human participants at Argosy University.

If, in the cooperative activity, an investigator from a cooperating institution desires to obtain direct access to any person at AU, the cooperative activity must be jointly reviewed, and

an AU faculty member must be listed on the research project request. Any restrictions imposed by the Argosy University IRB are binding on the outside investigator.

If, in the cooperative activity, an Argosy University faculty, staff member, employee, or student wishes to collect data from an outside agency, the principal investigator is responsible for submitting a letter indicating Certification to do such from an authorized member of the cooperative institution.

If the cooperating agency has its own IRB, Argosy University faculty, staff, employees, and students may be required to apply for Certification from and accommodate requests made from an outside IRB. That is, applicants for Argosy University IRB certification must have received approval from their institutions or superiors even if the research is outside their institutions.

Cross-campus Cooperative Research. In cases where cross-campus research is requested (more than one campus), the application must be filed with the chair of Argosy's National IRB. The National Chair will then convene a subcommittee of the full National IRB for review of the application. For most national requests, the convened subcommittee will include the chairs of the campus sites where the proposed research will take place. For national requests at the Full level, a quorum of the members of the National IRB will review the application at their next regularly-scheduled meeting.

Argosy Research at the National Level. In cases where research is requested at the National level, the applicant files an application with the Chair of Argosy's National IRB and the national IRB will review the materials, certifying where possible.

Permissions Required. At the National level, if a principal investigator seeks to use Argosy students, class practices or related educational materials, permission must be obtained from the university's Vice President for Academic Affairs (VPAA). If a principal investigator seeks to use Argosy employees or business practices at the national level as part of a study, permission must be obtained from the university's Vice President for Human Resources (VP of Human Resources) in consultation with the university's VPAA. In the principal investigator's request for permission, the principal investigator must explain in detail the purpose and procedures of the study and what is being requested from the school. The VPAA or VP of Human Resources will then either approve or deny the request in writing. National applications that do not contain the needed written permissions will be denied. Please note that OHRP

cautions against research using “participant pools of convenience,” and requests to use Argosy’s students, staff, educational or business practices, or faculty as research participants are only approved when the research provides a specific benefit to those being studied. Internal research conducted by Argosy at the national or local levels for purposes of program review, departmental assessment and university accreditation do not require IRB review, as these practices do not fall under the definition of research as per this handbook.

Changing Research Direction

On occasion, the principal investigator may foresee the possibility of changing directions in a study from archived data to gathering data from research participants. This kind of change requires the submission of a new Application for Certification of Compliance. To accommodate accelerated data gathering procedures, the principal investigator, through his or her faculty research supervisor may submit the new Application to the IRB chairperson and request interim certification to gather data under the strict supervision of the faculty research supervisor.

Action Research

Action Researcher(s), and all principal investigators, must follow the guidelines for collaboration with participants and other stakeholders as noted in the *Publication Manual of the American Psychological Association (Sixth Edition)*, the *Belmont Report* and *APA Code of Conduct* (Appendix Q of this Handbook).

Notification of IRB Decisions

Generally, the principal investigator and faculty research supervisor are notified of IRB decisions with the receipt of a signed copy of the Application. Requests for revisions will be sent through the faculty research supervisor. The Certification of Compliance is logged by the clerk and serves as official documentation that the research project has been certified. This documentation can be used for the dissertation proposal defense depending on campus procedures.

Interim Certification of Compliance

Interim Certification is reserved for research projects that may have immediacy for data collection.

If beginning a Full IRB Review (Level 3) study prior to the next scheduled monthly meeting of the IRB becomes essential--for example, when a patient with an unusual disorder suddenly becomes available for study and might suffer adversely by delay--the investigator may request interim certification. In such an instance, the investigator, through his or her faculty research supervisor, presents to the IRB chairperson a complete, signed application and a written request for interim certification, including the appropriate reasons for beginning the study before the next scheduled IRB meeting. The IRB chairperson (or the chairperson's designee) in consultation with at least one other IRB member will decide on the emergency interim compliance application. The interim certification is limited to the time until the next IRB meeting when the application will receive full Board review.

Interim conformance certification is neither appropriate nor will it be granted for purposes of meeting a grant or academic deadline or for the convenience of the applicant.

Continuing Review

All Certifications are Subject to Continuing Review

Any research activity involving the use of human participants that has received initial review and Certification by the IRB is subject to continuing review and Certification. Time intervals for such reviews shall be made at the discretion of the IRB, based on the risk to the participants, but shall occur no less than annually. It is the responsibility of the principal investigator to request an extension of Certification in a timely manner. Failure to adhere to these guidelines will be considered an act of non-compliance and the principal investigator could have research and/or funding suspended.

No human participant research may take place after the Certification expiration date without re-Certification. Failure to request re-Certification may result in disciplinary action.

A request for continuing certification (Appendix G) will normally occur during the eleventh month of a yearlong certification period and the subsequent Certification period will begin during that month. Continuing review for subsequent years will normally occur every 12

months, with the Certification period always beginning on the last day of the month in which the research project is reviewed. This procedure will ensure compliance with federal requirements and will ensure that research projects are reviewed “at least annually.”

Completing the Continuing Review Form

In completing the IRB Continuing Review Form, the principal investigator will report the condition of the research project, including the following:

1. Whether the study was initiated, and if not, indicate if the research project should be terminated;
2. If the conditions of certification or the project changed, including, for example, changes in the informed consent form or any other modifications to the study (any changes to the research project must be reviewed and Certified by the IRB);
3. If there have been any adverse events regarding human participants in the investigation (adverse events should be reported as required).

Submission of Continuing Review Form

The completed IRB Continuing Review Form is submitted by the principal investigator through his or her faculty research supervisor to the IRB with a copy of the original application. An IRB member designated by the IRB Chair or designated staff member will review the IRB Continuing Review Form and any other documentation submitted by the principal investigator as part of the continuing review report. One member may certify those who qualify under the Exempt or Expedited categories. No research may continue until Certification for continuation is granted. If full Board review is required, the original IRB application and a written status report of the research project and other supporting documents are copied and distributed to IRB members, and placed on the next available IRB meeting agenda.

After the full Board meeting, the Certification for Continuation is signed by the IRB chair and returned to the faculty research supervisor for forwarding to the principal investigator.

Those research projects qualifying for and receiving continuing Certification are reported to the IRB in a separate section of the agenda.

Continuing Review More Often than Annually

There are times when the risks associated with a particular research project are such that continuing review should take place more frequently than annually. These risks include the possibility of death, severe injury, major damage, or loss, or outcomes that may result in negative publicity for the participants involved. In these cases, the IRB may specify that the principal investigator report to the IRB either at a shorter time interval or after a specified number of participants is enrolled. The IRB may request the principal investigator to report the observed effects of the research activities and how the participant(s) responded to the research interventions. The IRB will determine if continued close monitoring of the research project is warranted, and, if so, will specify the period for monitoring.

Research Project Amendments or Modifications

Requests to modify or amend an IRB Certified research project, consent form, or any other document related to an IRB Certified research project must be made in writing by the principal investigator using an IRB Amendment Form (Appendix R). If revisions to the consent form are required, the principal investigator must submit two copies of the revised consent form with one copy noting where the changes were made using bolding, strike-through, or highlighting. These requests must come through the faculty research supervisor. The designated IRB member processes these requests. The forms are attached to the principal investigator's original IRB documents and appropriately filed.

Adverse Events

AU policy requires principal investigators to report promptly any adverse event related to the conduct of research, regardless of the severity.

An adverse event is defined as any potential for harm or any unanticipated problem(s) involving risks to participants or others. Such reports should be submitted to the principal investigator's faculty research supervisor immediately. The written report using an Adverse Event form (Appendix J) must be submitted to the designated IRB member within 10 days of the event.

All reports of adverse events are reported for review by the full Board at the next convened meeting. The designated reviewer or IRB Chair should specifically present especially serious events to the IRB at the next convened meeting.

Procedures to Ameliorate an Untoward Incident

Argosy University takes the position that any activity involving humans has the potential for an untoward incident. The risk of such incidents is controlled for in the principal investigator's procedures, but may still occur. The principal investigator is responsible for planning for a possible incident and for describing appropriate procedures in case an incident should occur. Being prepared to follow an employer's institutional procedures or school district procedures already in place constitutes appropriate planning.

Suspension of Certification

The IRB has the authority to suspend a project at any time for justifiable reasons, such as failure to comply with applicable state or federal regulations, adverse reactions to a study procedure or activity, or the inability to complete the study within the Certification period.

Preparation of Application Materials

All documents must be typed. All formatting and spacing should conform to the current edition of the APA Publication Manual. Applications and all materials submitted to the IRB should be carefully prepared and completely filled out. These materials become part of permanent records and are subject to inspection and review by various accrediting, granting, and government agencies.

Filing and Record Retention

All related continuation documentation, including new IRB Forms, copies of the new consent form, memoranda, and any other correspondence associated with continuing review will be appropriately filed with other documents submitted by the principal investigator. IRB records are maintained according to the records management system currently used by the University.

Section 4 contains various applications and documents presented as templates. Investigators are encouraged to select the appropriate application and other materials in consultation with their faculty research supervisors.

SECTION 3: IRB APPLICATIONS FORMS AND REPORTS

Application Forms for IRB Review of Research Projects Involving the Use of Human Participants

General Guidelines

The IRB's primary mission is to ensure the protection and ethical treatment of human participants in research conducted under the auspices of Argosy University. All students, faculty, staff, and administrators conducting research at Argosy University must first receive Certification of Compliance from the IRB before collecting data.

Note to investigators:

1. These forms have been formatted for completing and mailing electronically. Your campus location may require hard copy and/or electronic filing.
2. Select the appropriate form and save it to a file on your computer or other storage device.
3. You may use text from your research proposal to answer questions; DO NOT reference or attach your proposal to an application.
4. Future tense is appropriate.
5. Please answer every question on an application. N/A is an inappropriate answer for any question.
6. Incomplete forms will be returned and will extend the timeline for Certification.
7. Principal Investigators may communicate with the IRB through their faculty research supervisors.

Submitting an Application for IRB Review and Certification of Compliance:

Complete CITI training prior to completing the IRB application: the training will make determination of filing level easier. Determine the type of review appropriate to the content and procedures of the proposed research project: Exempt, Expedited, or Full IRB Review. Note that the entire application must be completed. Please consult this IRB handbook for definitions of what qualifies for an *Exempt* (Appendix A), *Expedited* (Appendix B), or *Full IRB Review* (Appendix C).

The procedures for submitting completed applications may vary from campus to campus (e.g., some may require the submission of multiple copies of the application; some may require the submission of an electronic application). Nonetheless, all campuses require the principal investigator to submit a completed application with faculty research supervisor's signature, a conflict of interest form, documentation of CITI completion, and the necessary supporting documentation. If applicable to the study, the following information must be submitted with an IRB application:

Copies of all informed consent documents that will be used in the research.

Depending on the type of consent being used, this might take the form of a formal informed consent document, an information sheet containing the elements of consent, or a copy of a script used to obtain verbal consent. Guidelines for creating a consent document can be found in this IRB manual and a sample consent form can be found in Appendix D. In addition to consent documents, any agreement documents used with minors must be attached to the application.

Permission letters. If data is being collected from another institution (e.g., hospital, school, clinic, etc.), the investigator is required to submit a signed letter from the appropriate official at that institution granting permission to do so.

Certification from other institutions. In the case that the institution has its own IRB and requires Certification from that IRB, the investigator must submit a Certification letter from that institution's IRB. Rarely, another institution may require local certification before granting their certification (Appendix F). Most often, other institutions request a letter stating that the applicant is affiliated with Argosy University, the name of the research study and the circumstance for which it is being conducted (e.g., the completion of doctoral requirements—dissertation) and the name and contact information of the faculty research supervisor.

In the instance that the other institution requires the Certification of Argosy University's IRB before considering requests, interim Certification may be requested, pending Certification from the other institution. In such a case, a final Certification letter from the other institution must be received before the study may proceed.

Study Materials. Copies of all advertisements, announcements, flyers, scripts, etc. that will be used to recruit participants must be submitted with the application. These recruitment materials must contain the name, phone, address of the investigator, and the purpose of the study,

eligibility requirements for participant, description of benefits, compensation, and location of the study.

Copies of all material provided to participants must be submitted with the application. This includes instruction forms, copies of all surveys or questionnaires that will be used, debriefing information, and planned questions for interviews. In the case of observational research, a copy of whatever coding form is used should be attached.

Permission for usage of previously collected data. If using archival data, the investigator must submit a letter from the owner of the data granting the investigator permission to use it. The letter must include an assurance that the data was initially collected in an ethical manner and that participants gave their consent for their information to be used for research purposes. The IRB may request a copy of the original consent form. If requesting an exempt review, the permission letter must also state that the data will be stripped of all identifying information before it is provided to the investigator.

Responding to a Request for Revisions

Following an IRB review, the investigator may be asked to make changes in the application or include additional information. Response to such requests should be made in a timely manner (30 days). When submitting revisions, the investigator should include a cover letter that points out exactly where in the documents the requested changes were made. The principal investigator should also return the memorandum requesting changes. This will help ensure a faster response. The revision should be returned to the investigator's faculty research supervisor. If approved, the faculty research supervisor returns the application to the clerk for logging and forwarding to the appropriate IRB member.

Request to Continue IRB Certification

When a research project is certified, the investigator will receive notification from the IRB. This notice will specify the period of time for which the research has been certified. Typically, research projects are certified for one year, though sometimes the period of certification can be shorter. Whenever the study is completed, the principal investigator is required to submit a completed copy of the Project Completion Form (Appendix Q) stating that the research was completed as planned. If the research is not completed before the period of

Certification expires, the investigator is required to submit a Continuing Review Form requesting an extension. The investigator may not continue to collect data after the period of Certification ends unless he or she receives a Continuance.

Research Project Amendments and Changes

All changes or amendments to a research project must be certified by the IRB before they can be implemented. To make a change, the investigator must complete the IRB Amendment Form (Appendix I or K) and submit it with any necessary supporting material. If making changes to existing documents (e.g., instructions, consent forms, etc.), the investigator should submit the new forms with the changes highlighted and explain what changes were made on the IRB Amendment Form. Amendments are submitted through the Faculty research supervisor.

Reporting Adverse Events

In the case of any significant deviation (accidental or otherwise) from the Certified research project, investigators are required, within 10 days of the incident, to submit an Adverse Event Report Form (Appendix J) to the IRB, along with any necessary supporting information. Any incidences in which participants are harmed or have otherwise adverse reactions to the research proceedings, must be immediately reported.

Elements of an Informed Consent Document

Every investigator at Argosy University must obtain the informed consent of any potential human participant of research before involving that person in research. Investigators must provide participants with informed consent documents written in simple, first person, lay language and in the native language understandable to the participant (or the participant's legally authorized representative). If participants do not read the native language in which the form is written, or if there is no written native language, then terms must be explained verbally in detail in their native language. Verbal consent must be documented and witnessed by another party who can speak the native language.

Parental consent is required of minors who have not attained 18 years of age. Parents cannot sign away a minor's right to choose to participate, and minors must give their assent

(even if parental consent is obtained). The investigator must provide minor participants with a separate form—called an agreement (or assent) form—written to the minors' level of understanding in simple language.

An example of a Consent Form is found in Appendix D. The investigator may create a consent form following the guidelines below or modify one of the sample forms. The consent form should be created in consultation with the faculty research supervisor and personalized to match the needs of the study.

Designing a Consent Form

The following elements must be included in the consent form(s), where appropriate.

1. The informed consent generally must be written in the first person (“I” of the participant) for example, “I understand that I will participate in a research study....” The informed consent must be written in simple, lay language. Word processing programs such as Microsoft Word can provide an estimate of the reading-level of documents (Tools, Spelling and Grammar Check).
2. The opening paragraph should state that it is a research study and give sufficient details for participants to be informed as to the purpose and objectives of the study (*if the study is part of degree requirements this must be clearly stated*); where the study will be conducted; and the duration, dates, and nature of participants' participation. Do not include a statement such as "I agree to what has been verbally described." The investigator must describe the study and its procedures on the informed consent document.
3. Description of the procedures to be followed, including any that are experimental; describe discomforts and risks. Specify the amount of time participation will take in terms of hours, days, weeks, etc.
4. Description of any risks (psychological, emotional, physical, etc.), however slight.
5. Description of any benefits to the person participating and available alternative procedures. If there are not any benefits for participation, indicate this also. Do not claim benefits to society or benefits to the investigator.

6. Description of compensation (monetary or psychotherapy benefits), schedule of payments, and compensation in the event of withdrawal from the study.
7. A statement informing participants if their medical records, grades, exam scores, or other personal documents will be examined or used.
8. Contact information for principal investigator, faculty research supervisor and IRB.
9. For survey, questionnaire, or other similar measurements, a statement informing participant(s) that they may refuse to answer (without loss of benefits to the participant) any questions that make them feel uncomfortable. If not answering questions would cause the principal investigator to have to withdraw the participant from the study, note this and any resulting consequences of being withdrawn, in the consent form.
10. For sensitive topics (e.g., depression, sex, AIDS/HIV, drug or alcohol abuse, suicide, abusive behavior, child abuse, etc.) the investigator must include sources where the participant can obtain assistance, such as counselors, treatment centers, or hospitals. Emphasize the plan of action for identified behaviors involving the risk of injury to self or others and for compliance with State and Federal reporting laws.
11. If appropriate, a statement that detected child abuse will be reported to the proper authorities.
12. A statement that participation is voluntary and that the participant can withdraw from the study at any time and that such withdrawal will not affect any treatment, employment, benefits, etc., if applicable. Specify the consequences or lack of consequences for withdrawing, (i.e., there will not be loss of benefits, grades, payment, treatment, course credit, employment, etc.).
13. A description of anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent, and what effect this termination would have on any benefits, payment, treatment, course credit, etc.
14. A statement that the study is confidential or anonymous--it cannot be both; explain how the investigator will maintain confidentiality of records and data (e.g., coded responses or secure storage). Confidential means that the information provided by the participant may be connected to the participant, whereas anonymous means that the information provided cannot be connected to the participant.
15. Permission for audio-videotaping, specifying how and by whom the tapes will be used, must appear in the consent form if taping will be part of the protocol. The investigator must let the

participants know how long the tapes will be kept and how the tapes will be destroyed or erased. If a participant refuses to be taped, but still may participate in the study, a separate form must be developed stating the options with a signature line for each option. If the study includes the videotaping of classrooms, the investigator must provide options to people who do not wish to participate or be video taped, such as allowing them to sit out of the videotape range, in back of the classroom, or letting them leave the room. (NOTE: A separate Audio-Video Tape release form should only be used in cases of deception studies in which participants are not informed that they have been AV taped until after their participation, or if the participant can still participate without being AV taped.)

16. A statement, if appropriate, that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable.
17. A listing of any additional costs the participant may incur while participating in the research, (e.g., parking fees, travel costs, medical costs, and loss of work time).

Oral informed consent may be Certified by the IRB in some cases if all elements of consent are given and the consent is witnessed or, in certain cases, audio or video taped. A transcript of the oral consent process must be provided to the IRB and must be given to the participant if they request a copy.

If the statement is longer than one page, each page must contain specific identifying details so that, in effect, the participant's signature is immediately below the statement of understanding. Consent forms with more than one (1) page should be initialed and dated by the participant (initial ____ date _____ on each page) and pages should be numbered (page x of y # of pages).

Additional Notes:

The final statements should be similar to the following: *I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. I have been given a copy of this consent form.*

The informed consent must be dated and have appropriate signatures. For parent's informed consent, include a line for the printed name of the child.

Give a signed copy of the informed consent document to the participant. *Collected consent forms must be kept in a locked, secure place.*

Provide the investigator's name, address, and telephone number, as well as those of another contact person. This means the graduate advisor, if the investigator is a graduate student; otherwise, provide the information for another responsible individual at Argosy University (insert campus name). Name, address, and phone number must be listed on the bottom of the form, so that participants know whom to contact for information on the study or in the event of a research-related injury to the participant. For safety, where possible, avoid using a principal investigator's home phone or address, instead providing a mailing address at the school (such as c/o the faculty research chair's work address).

Please note that the name of the study and the principal investigator's name should be in a header on each page of these forms. Also at the top of each page should be a page identifier as in Page 1 of 2.

SECTION 4: APPENDIXES

Appendix A

***Application for IRB Review and Certification of Compliance:
Exempt Application Form Checklist***

Exempt Review (Level 1) Application

No or Minimal Risk

(This level of application is reserved for research projects using archived data where there is no principal investigator-participant interaction.)

To the Principal Investigator of a research project:

1. *Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*
2. *If you are conducting a research project in another institution (e.g., a hospital or school), you must attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*
3. *If that institution also has a Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB)--then written permission from the participating institution's IRB must be attached to your IRB application.*
4. *If you are conducting research outside of the United States, you may not file at the Exempt level.*

Please check: The attached Application for Certification of Compliance contains

- Institutional Permission Letter (where data is held) or documentation of ability to use data
- Letter(s) of Informed Consent (may be needed if there is a question about use of data)
- Conflict of Interest Disclosure Statement
- CITI completion documentation for both Principal investigator and Faculty research supervisor
- Principal Investigator and Faculty Research Supervisor's signatures

***Application for IRB Review and Certification of Compliance
Exempt Cover Sheet***

IRB# _____
Date Logged: _____

*Use this form for research involving Archival Data or Literature Review
No or Minimal Risk*

(Review by one or more IRB Members — May lead to Expedited or Full review)

Principal Investigator/Researcher's Name: _____ Student ID Number: _____

Type of Research Project (CRP, Dissertation, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Telephone Number: _____ Email: _____

Faculty Research Supervisor/CRP/Dissertation Committee Chair's Name: _____

College: Business Psychological and Behavioral Sciences Education
Health Sciences OTHER

Program of Study: _____ Degree _____

Project Proposed Start Date: _____ Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or final completion date of project. I also attest that I will treat human participants' data ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator/Researcher _____ / _____
Date

Approval Signature – Faculty Research Supervisor/CRP/Dissertation Committee Chair:

_____ / _____
Date

IRB Certification
Signature _____ / _____

The above named research project is certified for compliance with Argosy University's requirements for the protection of human research participants with the following conditions:

- 1. Research must be conducted according to the research project that was certified by the IRB;*
- 2. Any changes to the research project, such as procedures, consent or assent forms, addition of participants, or study design must be reported to and certified by the IRB;*
- 3. Any adverse events or reactions must be reported to the IRB immediately;*
- 4. The research project is certified for the specific time period noted in this application; any collection of data from human participants after this time period is in violation of IRB policy.*
- 5. When the study is complete, the investigator must complete a Completion of Research form.*
- 6. Any future correspondence should be through the principal investigator's faculty research supervisor and include the assigned IRB research project number and the project title.*

NOTES:

- *Please complete this cover and the Application in detail. Every question must be answered. Please type your answers.*
- *Attach the appropriate documents and submit the entire application materials under the cover of a completed Application Checklist to the CRP or Dissertation Chair person.*
- *Do not proceed with any research work with participants until IRB certification is obtained.*
- *If any change occurs in the procedure, sample size, research focus, or other element of the project impacts participants, the IRB must be notified in writing with the appropriate form (see ancillary forms).*
- *Please allow 30 days after receipt of a complete application for processing.*
- **DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION**

***Application for IRB Review and Certification of Compliance
Exempt Application***

Exempt Review Application, No or Minimal Risk

(This level of application is generally reserved for research projects using archived data or literature reviews, where there is no principal investigator-participant interaction.)

In addition, the following conditions apply. Read and complete the following statements: If you answer “no” to both of the statements, your research does NOT qualify for Exempt status. (If your project does NOT qualify for Exempt status, complete an Expedited or Full application, based on risk/benefit ratio to participants).

- a. Any research that involves only archival data. Y N
- b. A literature review. Y N

Please completely answer the requested information (NA is not acceptable for any question). DO NOT attach your research proposal – answer the questions as stated.

Begin typing in the gray boxes.

1. Identify Study Site: _____
2. Brief but detailed summary of the project, including methodology: _____
3. Describe the nature of the involvement of human participants in the project.

4. Describe the nature of required institutional approvals or other approvals (parental approval as necessary according to institutional policy).

5. Describe how confidentiality will be maintained: Be specific, including the use of secondary documents, audio/video tapes, etc. Describe procedures for the safekeeping and disposal of information stored electronically.

6. Describe why this project fits the Exempt level of risk.

7. Describe review by institutions outside of Argosy University. (Attach copies of permission letters, IRB certifications, and any other relevant documents).

Attach any other required forms, including the principal investigator and faculty research supervisors' CITI completion forms, the principal investigator's Conflict of Interest form, tests, institutional permission slips, etc, related to this study. Failure to do so will result in delayed processing of the application.

Appendix B

***Application for IRB Review and Certification of Compliance:
Expedited Application Form Checklist***

Expedited Review (Level 2) Application, Moderate Risk

(Review by the designated IRB member or the IRB Chair).

Application Form Checklist

To the Principal Investigator of a research project:

1. *Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*
2. *Please be advised that research projects involving interaction with human participants must have an Informed Consent Form(s) attached. If a minor or incapacitated individual of any age is involved, parent/guardian permission must be included.*
3. *Parental permission does not negate the child's right to chose to not participate.*
4. *If you are conducting a research project in another institution (e.g., a hospital or school), you must attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*
5. *If that institution also has a Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB)-- then written permission from the participating institution's IRB must be attached to your IRB application.*
6. *If you are conducting the research outside of the United States, attach a letter of assurance that where the research is being conducted.*

Please check: The attached Application for Certification of Compliance contains

- Institutional Permission Letter (where research is taking place)
- Assurance of Adherence to Governmental Regulations concerning Human Subjects (if research project is conducted outside the US)
- Letter(s) of Informed Consent
- Parent/guardian Permission Letter (must have provision for written signature)
- Oral statement of Assurance (used with minors)
- Data-gathering instruments (s): Observation, Interview, Survey, other
- CITI completion documentation for both Principal investigator and Faculty research supervisor
- Conflict of Interest Disclosure Statement
- Principal Investigator and Faculty Research Supervisor's signatures.

***Application for IRB Review and Certification of Compliance
Expedited Cover Sheet***

IRB# _____
Date Logged: _____

Expedited Review (Level 2) Application, Moderate Risk

(Review by one or more IRB Members—May lead to Full IRB Review)

Principal Investigator/Researcher's Name: _____ Student ID Number: _____

Type of Research Project (CRP, Dissertation, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Telephone Number: _____ Email: _____

Faculty Research Supervisor's Name: _____

College: Business Psychological and Behavioral Sciences Education
Health Sciences OTHER

Program of Study: _____ Degree _____

Project Proposed Start Date: _____ Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or final completion date of project. I also attest that I will treat human participants ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator/Researcher _____ / _____
Date

Approval Signature – Faculty Research Supervisor/CRP/Dissertation Committee Chair:

_____ / _____
Date

IRB Certification
Signature _____ / _____

The above named research project is certified for compliance with Argosy University's requirements for the protection of human research participants with the following conditions:

1. *Research must be conducted according to the research project that was certified by the IRB.*
2. *Any changes to the research project, such as procedures, consent or assent forms, addition of participants, or study design must be reported to and certified by the IRB.*
3. *Any adverse events or reactions must be reported to the IRB immediately.*
4. *The research project is certified for the specific time period noted in this application; any collection of data from human participants after this time period is in violation of IRB policy.*
5. *When the study is complete, the investigator must complete a Completion of Research form.*
6. *Any future correspondence should be through the principal investigator's faculty research supervisor and include the assigned IRB research project number and the project title.*

NOTES:

- *Please complete this cover and the Petition in detail. Every question must be answered. Please type your answers.*
- *Attach the appropriate documents and submit the entire application materials under the cover of a completed Application Checklist to the CRP or Dissertation Chairperson.*
- *Do not proceed with any research work with participants until IRB Certification is obtained.*
- *If any change occurs in the procedure, sample size, research focus, or other element of the project impacts participants, the IRB must be notified in writing with the appropriate form (see ancillary forms).*
- *Please allow 30 days after receipt of a complete application for processing.*
- **DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION**

Application for IRB Certification of Compliance

Expedited Application

Expedited Review (Level 2) Application, Moderate Risk

(Review by one or more IRB Members— May lead to Full Review)

Research with minors, prisoners, mentally/emotionally/physically challenged persons, pregnant women, fetuses, in vitro fertilization, and/or individual or group studies where the investigator manipulates the participants/ behavior or the participant is exposed to stressful or invasive experiences do(es) not qualify for Expedited status.

Please completely answer the requested information (NA is not acceptable for any question). DO NOT attach your research proposal – answer each specific question in the area provided. Begin typing in the gray boxes.

1. Purpose of the Study: _____
2. Summary of the Study. Methodology (Be Specific).

3. Participant Demographics:
 - a. Anticipated Sample Size: _____
 - b. Special Ethnic Groups (describe): _____
 - c. Institutionalized Y N Protected Group (describe): _____
 - d. Age group: _____
 - e. General State of Health: _____
 - f. Other details to describe sample group. _____
4. Will deception be used in the study? Y N (please describe) _____
5. Will audio or videotapes be used in the study? Y N (please explain) _____

6. Confidentiality protection issues (pertains to audio and video as well as written documents.)
 - a. What precautions will be taken to insure the privacy and anonymity of the participants? (i.e. closed doors, private rooms, handling of materials where participant's identify could be discovered, etc.). _____
 - b. What specific precautions will be taken to safeguard and protect participant's confidentiality while handling the data (audio/video/paper) both in principal investigator's possession and in reporting the findings? (i.e., coding, removal of identifying data). _____
 - c. Describe procedures where confidentiality may be broken by law (e.g., child abuse, suicidal intent). _____

7. Review by institutions outside of Argosy University/XX Y N (Attach copies of permission letters, IRB certifications, and any other relevant documents). _____

8. Informed Consent and Assent (Attach copies of all relevant forms). If consent is not necessary (e.g., anonymous interview), describe how you will inform all participants of the elements of consent (see instructions). _____

9. If written or oral informed consent is required, describe the manner in which consent and/or assent was obtained for each level).
 - (a) Adult Participants (18 years and older – written consent required). _____
 - (b) Child Participants (under 18 – parent/guardian permission and participant assent required). _____
 - (c) Institutionalized participants (parent/guardian/conservator permission with appropriate participant assent). _____

10. Describe any possible physical, psychological, social, legal, economic or other risks to

participants. _____

- a. Describe the precautions taken to minimize risk to participants. _____
- b. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies). _____

11. Potential benefit of the study:

- a. Assess the potential benefit(s) of the study for the participants: _____
- b. Assess the potential benefits(s) to the professional community: _____

Attach any other required forms, including the principal investigator and faculty research supervisors' CITI completion forms, the principal investigator's Conflict of Interest form, tests, institutional permission slips, etc, related to this study. Failure to do so will result in delayed processing of the application.

Appendix C

***Application for IRB Review and Certification of Compliance
Full Application Form Checklist***

Full IRB Review (Level 3) Application, High Risk

(Full Board Review)

Application Form Checklist

To the Principal Investigator of a research project:

1. *Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*
2. *Please be advised that research projects involving interaction with human participants must have an Informed Consent Form(s) attached. If a minor or incapacitated individual of any age is involved, parent/guardian permission must be noted and included.*
3. *Parental permission does not negate the child's right to chose to not participate.*
4. *If you are conducting a research project in another institution (e.g., a hospital or school), you **must** attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*
5. *If that institution also has a Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB) -- then written permission from the participating institution's IRB must be attached to your IRB application.*
6. *If you are conducting the research outside of the United States, attach a letter of assurance that you will abide by the laws and regulations of the governing bodies that preside over the location where the research is being conducted.*

Please check: The attached Application for Certification of Compliance contains

- Institutional Permission Letter (where research is taking place)
- Assurance of Adherence to Governmental Regulations concerning Human Subjects/Participants (if research project is conducted outside the US)
- Letter(s) of Informed Consent
- Parent/guardian Permission Letter (must have provision for written signature)
- Oral statement of Assurance (used with minors)
- Data-gathering instruments (s): Observation, Interview, Survey
- Conflict of Interest Disclosure Statement
- CITI completion documentation for both Principal investigator and Faculty Research Supervisor
- Principal Investigator and Faculty Research Supervisor's signatures.

***Application for IRB Review and Certification of Compliance:
Full Cover Letter***

*Full IRB Review (Level 3) Application, High Risk
(Full Board Review)*

IRB# _____

Date Logged: _____

Principal Investigator/Researcher's Name: _____ Student ID Number: _____

Type of Research Project (CRP, Dissertation, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Telephone Number: _____ Email: _____

Faculty research supervisor/CRP/Dissertation Committee Chair's Name: _____

College: Business Psychological and Behavioral Sciences Education
Health Sciences OTHER

Program of Study: _____ Degree _____

Project Proposed Start Date: _____ Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or final completion date of project. I also attest that I will treat human participants ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator/Researcher _____ / _____
Date

Approval Signature – Faculty Research Supervisor/CRP/Dissertation Committee Chair:

_____ / _____
Date

IRB Certification
Signature _____ / _____

The above named research project is certified for compliance with Argosy University's requirements for the protection of human research participants with the following conditions:

1. *Research must be conducted according to the research project that was certified by the IRB.*
2. *Any changes to the research project, such as procedures, consent or assent forms, addition of participants, or study design must be reported to and certified by the IRB.*
3. *Any adverse events or reactions must be reported to the IRB immediately.*
4. *The research project is certified for the specific time period noted in this application; any collection of data from human participants after this time period is in violation of IRB policy.*
5. *When the study is complete, the investigator must complete a Completion of Research form.*
6. *Any future correspondence should be through the principal investigator's faculty research supervisor and include the assigned IRB research project number and the project title.*

NOTES:

- *Please complete this cover and the Application in detail. Every question must be answered. Please type your answers.*
 - *Attach the appropriate documents and submit the entire application materials under the cover of a completed Application Checklist to the CRP/Dissertation Chairperson.*
 - *Do not proceed with any research work with participants until IRB certification is obtained.*
 - *If any change occurs in the procedure, sample size, research focus, or other element of the project impacts participants, the IRB must be notified in writing with the appropriate form (see ancillary forms).*
 - *Please allow up to 60 days after receipt of a complete application for processing.*
- DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION**

***Application for IRB Certification of Compliance:
Full Application***

Full IRB Review (Level 3) Application, High Risk or Involving Vulnerable Populations

Vulnerable populations include children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons.

Please completely answer the requested information (NA is not acceptable for any question). DO NOT attach your research proposal – answer each specific question in the area provided.

Begin typing in the gray box.

1. Purpose of the Study: _____
2. Brief but detailed summary of the project, including methodology. _____
3. Participant Demographics:
 - a. Anticipated Sample Size: _____
 - b. Special Ethnic Groups (describe): _____
 - c. Institutionalized Y N Protected Group (describe): _____
 - d. Age group: _____
 - e. General State of Health: _____
 - f. Other details to describe sample group: _____
4. Will deception be used in the study? Y N (please describe)

5. Will audio or videotapes be used in the study? Y N (please explain)

6. Confidentiality protection issues (pertains to audio and video as well as written documents.)
 - a. What precautions will be taken to insure the privacy and anonymity of the participants? (i.e., closed doors, private rooms, handling of materials where a participant's identify could be discovered, etc.).

- b. What specific precautions will be taken to safeguard and protect subject's confidentiality while handling the data (audio/video/paper) both in principal investigator's possession and in reporting the findings? (i.e., coding, removal of identifying data). Describe procedures for the safekeeping and disposal of information stored electronically. _____
- c. Describe procedures where confidentiality may be broken by law (e.g., child abuse, suicidal intent).

7. Review by institutions outside of Argosy University/name of the campus. (Attach copies of permission letters, IRB certifications, and any other relevant documents).

8. Informed Consent and Assent (Attach copies of all relevant forms). If consent is not necessary (e.g., anonymous interview), describe how you will inform all participants of the elements of consent.

9. If written or oral informed consent is required, describe the manner in which consent and/or assent was obtained for each level).
- (d) Adult Participants (18 years and older – written consent required). _____
- (e) Child Participants (under 18 – parent/guardian consent and participant assent required). _____
- (f) Institutionalized participants (parent/guardian/conservator consent with appropriate participant assent). _____
10. Describe any possible physical, psychological, social, legal, economic or other risks to participants (Attach another page if needed).

- a. Describe the precautions taken to minimize risk to participants.

- b. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies).

11. Potential benefit of the study:

- a. Assess the potential benefit(s) of the study for the participants:

- b. Assess the potential benefits(s) to the professional community:
-

Attach any other required forms, including the principal investigator and faculty research supervisors' CITI completion forms, the principal investigator's Conflict of Interest form, tests, institutional permission slips, etc, related to this study. Failure to do so will result in delayed processing of the application.

Appendix D

Sample Basic Consent Form

CONSENT FORM

(Insert Title of Study)

I have been asked to participate in a research study (*Insert general statement about study, including if it is a degree requirement*). I was asked to be a possible participant because (*Explain how participant was identified*). A total of (*Insert number of test subjects*) people have been asked to participate in this study. The purpose of this study is (*Explain research question and purpose in lay language*).

If I agree to be in this study, I will be asked to (*Explain tasks and procedures: Participants should be told about video or audio taping, if participation will be affected if participant does not want to be video or audio taped, and assignment to study groups where applicable*) This study will only take (*Insert length of time for participation, frequency of procedures, etc.*) The risks associated with this study are (*Risk must be explained, including the likelihood of the risk*). The benefits of participation are (*Insert benefit(s); if no benefits, state that fact here.*)

I will receive (*Insert payment or reimbursement information, if no monetary compensation, state that fact here. If participants receive class points or some other token, include that information here and alternative task in case participant does not want to participate in study but wants to obtain class points. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdrawal.*) This study is (*anonymous or confidential – it cannot be both -- and describe how this will be accomplished*). The records of this study will be kept private. No words linking me to the study will be included in any sort of report that might be published. Research records will be stored securely and only (*Insert names of individuals who will have access to this data*) will have access to the records. (*If tape recording or videotapes are made, explain who will transcribe the tapes, who will have access, if they will be used for education purposes, and when they will be erased.*) I have the right to get a summary of the results of this research if I would like to have them.

I understand that my participation is strictly voluntary. My decision regarding my participation will not affect my current or future relations with Argosy University (*include any other cooperating institutions, insert names here*). If I decide to participate, I am free to refuse to answer any of the questions that may make me uncomfortable. I can withdraw at any time without my relations with the university, job, benefits, etc., being affected. I can contact (*Insert your name and contact information and advisors name and contact information*) with any questions about this study.

I understand that this research study has been reviewed and Certified by the Institutional Review Board, Argosy University – (*Insert location*). For research-related problems or questions regarding participants' rights, I can contact the Institutional Board at (*Insert contact info*).

I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. I have been given a copy of this consent form. By signing this document, I consent to participate in the study.

Name of Participant (printed) _____

Signature: _____ Date: _____

Signature of Principal Investigator: _____

Date: _____

Information to identify and contact investigator (address, telephone, etc.)

Add if seeking consent for a minor (under age 18) to participate

If giving consent for a Minor Child to participate, print child's name: _____

Relationship to Child (please identify the relationship)

Legal Guardian (appointed by) _____

Note: All informed consent statements should be designed to meet the needs of each individual research project and / or sample group and are therefore subject to change as needed.

Approval by parents does not sign away or negate the right of children to refuse to participate.
--

Each child's assent form must contain the above elements, state that participation is voluntary, and permit the child to refuse to participate.

Alternative Consent Form

Use these as model statements for survey/interview cover sheets or as introductory statements (according to your chairperson)

Dear _____,

You are cordially invited to participate in a research study. The purpose of this research study is to *(briefly describe the purpose of your study, including that the research study is a degree requirement)*. You are being asked to participate because *(describe why this participant was selected)*. If you participate in this research, you will be asked to *(describe what your participants will be asked to do, what information they will be asked to provide--demographic, attitudinal, test scores, physical measures, etc., and describe any potential risks or discomforts to the participant)*.

Your participation will take approximately *(insert approx. length of time needed to participate and/or duration of the project itself)*.

Your participation in this research is strictly voluntary. You may refuse to participate at all, or choose to stop your participation at any point in the research, without fear of penalty or negative consequences of any kind.

The information/data you provide for this research will be treated confidentially, and all raw data will be kept in a secured file by the principal investigator. Results of the research will be reported as aggregate summary data only, and no individually identifiable information will be presented. *(Note - These statements must be true. If you cannot abide by these procedures for assuring confidentiality, you must describe the procedures you will follow.)*

You also have the right to review the results of the research if you wish to do so. A copy of the results may be obtained by contacting the principal investigator at the address below:

(Insert your name and mailing address here.)

There will be no direct or immediate personal benefits from your participation in this research. *(Describe any benefits to the participant personally, if any exist. Otherwise, insert the "No direct or immediate" statement.)*

Or use: the results of the research may contribute *(Describe any potential benefits practical or theoretical) to the field, the profession, or to society as a whole.*

I understand that this research study has been reviewed and Certified by the Institutional Review Board, Argosy University – (*Insert location*). For research-related problems or questions regarding participants' rights, I can contact Argosy's Institutional Board at (*Insert contact info*).

I have read and understand the information explaining the purpose of this research and my rights and responsibilities as a participant. My signature below designates my consent to participate in this research study, according to the terms and conditions outlined above.

Signature _____ Date _____

Print Name: _____

(The participant should retain one of the two copies of the consent letter provided by the principal investigator.)

If giving permission for your minor child to participate in the research study, please print the child's name here: _____

Relationship to Child (*circle*) Male Parent Female Parent

Male Grandparent Female Grandparent

Other Male Relative Other Female Relative

(*specify*) _____ (*specify*) _____

Legal Guardian (*appointed by*) _____

Please note that children under 18 years of age must have parental permission to participate in a research study and that a separate assent (agreement) form or statement is required for the child's participation. That statement may be included in this form or attached as a separate document.

Note: All informed consent statements should be designed to meet the need of each individual research project and/or sample group and are, therefore, subject to change as needed.

Model Oral Instructions to Participants Involved in Survey Research

Note: The following statement (because it is included in the letter of consent) may be included on the first page of a paper survey. This statement must be included in online surveys.

The purpose of this research study is to (*fill in the blank - e.g., "compare opinions, examine perceptions, etc."*). By completing and submitting this survey, you are giving your consent for the principal investigator to include your responses in his/her data analysis. Your participation in this research study is strictly voluntary, and you may choose not to participate without fear of penalty

or any negative consequences. Individual responses will be treated confidentially. No individually identifiable information will be disclosed or published, and all results will be presented as aggregate, summary data. If you wish, you may request a copy of the results of this research study by writing to the principal investigator at *(fill in your name and address here)*.

Appendix E

*Letter to Correct IRB Application Deficiencies**IRB MEMORANDUM**Argosy University*

Date:

To: Faculty Research Supervisor

For: Principal Investigator

From:

IRB Member

Re: Incomplete Application for IRB Certification

Please return this application to the principal investigator to be completed and/or revised for the following reasons:

Original Institutional Permission Letter missing or unsigned (required on letterhead)

Comments:

Letter of Informed Consent missing or needs revision

Comments:

Missing signatures

Question(s) not answered/ not complete or unclear

Comments:

Missing attachment (Interview/Survey)

Other:

When the revised application is returned to you and you deem it complete, please sign/initial, and date as appropriate return it to the IRB chair or administrative assistant for logging.

Appendix F

Letter to Other Institutions Which Have Requested Argosy Certification First

Chair, Institutional Review Board
XXXXX University
XXXXXX, XXX

Dear IRB Chairperson:

XXXXX is a graduate student at Argosy University/ XXXXXX working on his dissertation under the supervision of Dr. XXXXXX, his faculty research supervisor.

A requirement to proceed with his studies is his dissertation committee's approval of his proposal, which is predicated on his ability to conduct his research. In addition, one factor of that ability to conduct research is the approval of the institution where the research will be conducted. Our IRB would not presume that the study meets that standards of the supervising institution and, therefore, has required that students secure local institutional approval first as part of our review.

Thank you for your consideration.

Sincerely,

Note: On a rare occasion, the full IRB may issue a "Contingent Certification" pending receipt of approval/certification from the principal investigator's institution. This letter may be modified to provide for that condition.

Appendix G

Continuing Certification of Compliance

IRB Research project #:

Date of Original Certification:

Date Submitted:

REQUEST FOR CONTINUING CERTIFICATION OF COMPLIANCE

(Submit to the Institutional Review Board, including all requested materials.)

Please provide the following information regarding your study. Each item must be filled in or indicated as non-applicable:

(PLEASE TYPE)

Principal Investigator:

Faculty research supervisor:

Title of Project:

Please check the following items as they may apply to your project during the period following IRB review:

1. The study was not initiated and has been cancelled *(please indicate here and return the form with a completed signature page)*:
2. A renewal of the research project is requested:
 - a. Renewal of proposal or research project with no changes. The research project has not yet been begun but will be carried out as previously certified.
 - b. The research is in progress and no changes in research project have been made regarding human participants.
 - c. The research project was modified during the project. *(Any changes to the research project must be reviewed and Certified by the IRB before being initiated.)* Please attach certified amendment forms.
3. Have there been any adverse events regarding human participants in your investigation?

Appendix H

Project Completion Report
(use for notification of completion for research projects certified by an Argosy IRB)

Type all answers

1. General Information

Principal Investigator:

Address:

College:

Telephone/Fax:

Email: _____

Signature of Faculty Research Supervisor/Date _____

2. Title of Project:

3. Date of Completion

4. Summary of Outcome:

Appendix I

Amendment to Original IRB Certification

IRB Research project #:

Date of Original Certification:

Date Submitted:

(Submit to the Institutional Review Board, including all requested materials.)

Please provide the following information regarding your study. Each item must be filled in or indicated as non-applicable:

(PLEASE TYPE)

Principal Investigator:

Faculty research supervisor:

Title of Project:

1. Description of Changes to the research project (*check all that apply*):

- a. Revision to research project
- b. Revision to consent documents
- c. Other (specify)

2. Describe the specific changes being requested:

3. How have the requested changes impacted the level of risk involved for participants?

4. Attach revised research project and or consent documents as applicable (*make sure all changes are highlighted and or in bold type*)

I/We certify that the above statements and attachments concerning this research are true.

Principle Investigator_____
Signature_____
Date_____
Faculty Research Supervisor_____
Signature_____
Date

Appendix J

Adverse Event Report

IRB Research project #:

Date of Original Certification:

Date Submitted:

Adverse event refers to any event, circumstance or occurrence that was not anticipated or accounted for in the original IRB application and that may have a negative impact on the research project as a whole.

(Submit to the Institutional Review Board, including all requested materials.)

(PLEASE TYPE)

Principal Investigator:

Faculty research supervisor:

Title of Project:

1. Date of Event:

2. Describe the Adverse Event

3. Attach a summary of all circumstances related to this event. All hospitalization and/or medical treatment must be reported. Include all notifications, correspondence, and other related materials of this adverse event from the study sponsor or study sites. Include a statement regarding this adverse event and its relation to the study at Argosy University.

I/We certify that the above statements and attachments concerning this research are true.

 Principal Investigator

 Signature

 Date

 Faculty Research Supervisor

 Signature

 Date

Appendix K

Change in Procedure Application (Use for Minor Change)

IRB#
Date Received

(Submit Appendix I: Amendment to Original Certification for a Major Change)

Please type all answers

NOT TO BE USED TO CHANGE PRINCIPAL INVESTIGATOR

Date of last IRB review:

Was additional institutional approval originally obtained?

(e.g., from School, Hospital, etc.)

Y N (If Yes, please attach).

Please check appropriate changes:

- Addition
 Revision
 New Title
 Revised Informed Consent
 Other

(Attach a complete copy of the original application with all additions/revisions/changes highlighted.)

1. General Information

Principal Investigator:

Address:

Telephone/Fax #:

Email:

Dept. /College

Committee Members

2. Project Information

Title of Project:

3. Amendment Information - Please Complete Entire Section. DO NOT attach your research proposal
- Describe the proposed additions/revisions in appropriate detail:
 - Describe any significant change in the risk/benefits for the participants from these additions/revisions:
 - Have you revised the Informed Consent to include any of the additions/revisions?

Y N If yes, please attach a copy of the revised consent form and highlight all revisions.

4. Change in Dissertation Committee Membership

Your acknowledgment is requested to assure the Argosy University/XXXX Institutional Review Board that you are aware of the existence and status of this research activity and that you agree to the statements made in the original IRB application including the "Statement of Assurance."

Signature of Faculty Research Supervisor/ Signature Date
(Print Name)

Committee Member (Print Name) Committee Member Signature Date

Committee Member (Print Name) Committee Member Signature Date

5. Principal Investigator Statement of Assurance

"I understand that I cannot initiate any changes in my Certified protocol/research project before I have received Re-certification and/or complied with all contingencies made in connection with that approval."

Signature of Principal Investigator Date

Please return this application and any attachments to:

Attn: Institutional Review Board Argosy University _____

form is accurate, and that every effort has been made to provide the reviewers with complete and accurate information related to the nature and procedures to be followed in this research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), participant selection process, change of research coordinator (course instructor), adverse incidents, and/or final completion of projects. I agree to file a Progress Report with the IRB at the end of each term in which this project has been implemented. I also agree to abide by all governmental regulations and institutional policies that apply to this study, including those applicable to research work conducted in countries other than the United States.

Course Instructor's Signature:	Date:
--------------------------------	-------

Attach any other forms, tests, institutional permission slips, etc., relative to this study. Failure to do so may result in delayed processing of the application.

Important Notice:

- *Please complete this form in detail, sign it, then submit the form to your departmental IRB representative with attachments relevant to this project.*
- *Do not distribute this assignment to students until IRB certification is obtained.*
- *If any change occurs in any element of the project, the IRB must be notified in writing with the appropriate form.*
- *Please allow 30 days after receipt of a complete application for processing.*
- *Certification is for one year.*

Attach the appropriate Application for IRB Review and Certification of Compliance.

Appendix M

Assigned Course Research Progress Report

***TO BE FILED WITH THE IRB AT THE END OF EACH TERM
IN WHICH A CERTIFIED CLASS PROJECT HAS BEEN IMPLEMENTED.***

IRB Number:	Date of Initial Certification:
-------------	--------------------------------

Type all answers

1. General Information

Course Instructor:
Department / College:
Course Number and Title:
Section/Term:
Student Researchers: <i>You may attach a class roster if all students completed this project.</i>

2. Project Information

Title of Project:

3. Continuing/Final Report Information

Number of participants participating for this class only:
Have any participants withdrawn or dropped out? YES NO

If YES please provide a brief summary including number of drop-outs and circumstances leading up to their withdrawal from the project.

4. Research Coordinator (Course Instructor) Statement of Assurance

I understand that additions to or changes in procedures involving human participants, as well as any problems connected with the use of human participants once the study has been certified by the Institutional Review Board, must be reported in writing to the IRB.

I agree to provide reasonable and appropriate oversight to ensure that the rights and welfare of the human participants are properly protected.

Course Instructor's Signature:	Date:
--------------------------------	-------

Please return this application and any attachments to:

Attn: Institutional Review Board
 Argosy University _____
 Institutional Review Board (IRB)

Appendix N

*IRB Organizing Letter: IRB Letter of Assurance***ARGOSY
UNIVERSITY****XXXXXX Campus**

To Dr. XXXXXXX, President, Argosy University/XXXXXX September XX, 20XX

INSTITUTIONAL REVIEW BOARD LETTER OF ASSURANCE

At its Organizational Meeting, (indicate date of meeting), the undersigned agreed to comply with the guidelines and procedures established for the IRB as outlined in the campus and National Institutional Review Board Handbook.

Members of the Argosy University/XXXXXX
Institutional Review Board for 20xx-20xx

Name	Signature	Position	Affiliation
Dr. xxxxxxx		Chair	AUX School of Psychology and Behavioral Sciences
Dr. xxxxxxx		Member	College of Business and Information Technology
Dr. xxxxxxx		Member	AUX School of Psychology and Behavioral Sciences
Dr. xxxxxxx		Member	College of Education and Human Development
Dr. xxxxxxx		Member	(Describe Department or Position)
			Non-Affiliated

Schedule of Meetings for 20xx

(Indicate planned schedule: e.g. First Monday of Month)

All meetings are scheduled for (indicate time and location).

(Provide a list of specific dates when the board will meet)

Appendix O

IRB Procedural Forms (Examples)*Example Logging Format*

(Table or Excel). May be copied, pasted and adjusted. Landscape works well.

IRB#	DATE APPLICATION RECEIVED	FILING LEVEL	STUDENT NAME	CHAIR	DATE CERTIFIED	TITLE OF PROJECT
------	---------------------------	--------------	--------------	-------	----------------	------------------

Note this format can be modified with “received,” “Change of Procedure/Certified,” or “Completion Report Date” or other similar categories.

Appendix P

EDMC Code of Business Ethics and Conduct

Conflicts of Interest

EDMC's directors and employees must be free of conflicting interests that might influence, or be perceived to influence, their decisions when representing EDMC. Consequently, you must not maintain any interest that conflicts with the interests of EDMC, and should make every effort to avoid even the appearance of any such conflict.

A "conflict of interest" occurs when your private interest interferes in any way, or even appears to interfere, with EDMC's interests as a whole. A conflict of interest can arise when:

- a. you take actions or have interests that may make it difficult to perform your work on behalf of EDMC objectively and effectively;
- b. you, or a member of your family, receive any improper personal benefits as a result of your position with EDMC.

Employees who believe that they may have a potential conflict of interest must report their concerns to the General Counsel immediately. Directors or executive officers who believe that they may have a potential conflict of interest must report their concerns to the Chairman of the Board, who will consult with the Nominating and Corporate Governance Committee to resolve the situation.

Following are guidelines that will help you recognize and avoid potential conflicts of interest. Please remember that conflicts of interest are not restricted to these guidelines.

- a. Your dealings with students, employers of our graduates, suppliers, contractors and others should be based solely on what is in EDMC's best interest, without favor or preference to any third party, including close relatives.
- b. If you deal with, or influence decisions of, individuals or organizations seeking to do business with EDMC, you must not own interests in, or have other personal stakes in, those organizations that might affect your decision-making process and/or objectivity.
- c. You must not do business with close relatives on behalf of EDMC unless you have disclosed the relationship and received written authorization.
- d. Personal loans, or any guarantee of such loans, by EDMC to you or to members of your families are strictly prohibited.

e. Unless you have received approval in writing from your supervisor, you must not accept or attempt to accept costly entertainment or gifts from third parties with whom EDMC directly or indirectly does, has, or is seeking to do business. The following direct and indirect forms of compensation are strictly prohibited:

- separate individual payment or commission arrangements;
- personal loans or services;
- excessive entertainment and travel;
- gifts of more than nominal value.

If such a gift is unavoidable because of local custom, you must report the gift to the General Counsel, who may consult with the Nominating and Corporate Governance Committee, for a determination whether, or the extent to which, the gift may properly be considered your personal property.

Example Conflict of Interest (Disclosure) Statement

To the Institutional Review Board:

I have reviewed the *EDMC Code of Business Ethics and Conduct Statement* found in APPENDIX P of the *Argosy University Institutional Review Board Handbook* and wish to disclose the following potential conflict of interest related to my research study:

OR

I have reviewed the *EDMC Code of Business Ethics and Conduct Statement* found in APPENDIX P of the *Argosy University Institutional Review Board Handbook* and state that I have no potential conflicting interests that might influence or be perceived to influence how I professionally conduct my research study.

Signed and Dated (under printed name).



Appendix Q

Additional Resources

The American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct -- <http://www.apa.org/ethics/code/index.aspx>

CITI Training -- <http://citiprogram.org>

Code of Federal Regulations, Title 45, Part 46 (CFR Title 45, Part 46, 1991) -- <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

The Belmont Report -- <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>