Appendix F: IRB Policies, Regulations, and Rules

Aspen University Institutional Review Board (IRB) follows the OHRP IRB Guidebook, which provides a basic understanding of the background and purposes of the IRB review system. The following is a general overview of the considerations to be followed in a research undertaking involving human subjects.

Regulatory Compliance Administrator, Office of Sponsored Programs and Regulatory Compliance (919-515-4514) REG10.10.3

Additional References: Department of Health and Human Services, National Institutes of Health, Office for References: Protection from Research Risks, CFR 45, PART 46, Protection of Human Subjects, Revised November 13, 2001, Effective December 13, 2001; Institutional Review Board for the Protection of Human Subjects in Research ; University Requirement for the participation and administration of projects conducted with Human Subjects; Code of Federal Regulations Title 45 - Part 46 - Protection of Human Subjects; OHRP - Office of Human Research Protection; OHRP IRB Guidebook; 5 U.S.C. 301; Sec. 474(a), 88 Stat. 352 (42 U.S.C. 2891-3(a)).

1. General

Federal law and University policy require that all research involving human subjects, conducted by ASPEN UNIVERSITY researchers (e.g., Professors/Faculty Chairs, students, DRPH reviewers, and staff) must be reviewed and approved by the Institutional Review Board (IRB) for the Use of Human Subjects in Research. These rules are in place to protect the human subjects, the researchers, and the institution. The IRB may be accessed through email (irb@aspen.edu).

2. General Principles

All ASPEN UNIVERSITY researchers must adhere to strict ethical standards for the use of human subjects in their research. These standards are in place to protect the basic rights of their subjects. Any research that departs from the spirit of these standards violates University policy. Below are some guidelines that the IRB members consider during their reviews to maintain these standards.

2.1. All research procedures minimize the risks to subjects.

2.2. Any risk must be reasonable in relation to the potential benefits from the study.

2.3. Informed consent must be obtained from the subject before participation. This consent must be in writing unless exempted by the committee.

2.4. Subject must be provided with adequate detail regarding the study to make an informed decision regarding their participation. This information should be included on the consent form and should be written in lay language, so that the subjects can make an informed decision regarding participation.

2.5. Subject’s privacy must be maintained.

2.6. Subjects need to be made aware that they participate of their own choice and are free to withdraw from the study at any time

3. Review Categories

There are three categories (or types of review) for projects that are submitted to the IRB:

3.1. Exempt Review (no human subjects)

3.2. Expedited Review (appropriate use of human subjects)

3.3. Full Review (potential inappropriate use of human subjects)

Upon submission to the IRB, the serving Faculty Chair makes a recommendation for type of review. Final determination of the type of review is made by the Chair of the IRB upon consideration of the submitted materials. *Exempt* reviews (1-2 weeks) are typically conducted on those studies that involve no human subjects. *Expedited* reviews (2-4 weeks) involve review by two or three IRB committee members where human subjects are involved. *Full* reviews (4-6 weeks) involve the entire IRB committee and perhaps external experts. The type of review conducted is checked on the approval form once the review has ended and the findings and recommendations are reported to the Faculty Chair for discussion with the Doctoral Student.

4. Definitions

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

4.2. Human Subject - Means a living individual, about whom an investigator (whether professional or student) conducting research obtains:

4.2.1. Data through intervention or interaction with the individual; or

4.2.2. Identifiable private information

4.2.3. Intervention includes both physical procedures, by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

4.4.4. Private information includes information about behavior that occurs in a context, in which an individual can reasonably expect that no observation or recording is taking place, and information, which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, an academic record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information), in order for obtaining the information to constitute research involving human subjects.

4.2.5. IRB Approval - the determination of the IRB that the research has been reviewed and may be conducted at ASPEN UNIVERSITY within the constraints set forth by the IRB, and by other institutional and federal requirements.

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

5. Procedures

5.1. Approval Processes - Described below is the process by which a principal investigator seeks approval from the IRB for the Use of Human Subjects in Research.

The following definitions are used:

5.1.1. Forms - There are four components to a package to be submitted to the IRB for review: the cover sheet, the preliminary questions sheet, the proposal narrative, and the informed consent form.

5.1.1a. Cover Sheet - The cover sheet provides basic information regarding the study under consideration and the principal investigator(s). For research whose principal investigator is a member of the ASPEN UNIVERSITY faculty, this form should be completed, and the ASPEN UNIVERSITY faculty member must sign attesting to their awareness of the University's policies and procedures for the use of human subjects in research. For research whose principal investigator is not a member of the ASPEN UNIVERSITY faculty, such as the Doctoral Student, this form should be completed, and the principal investigator must sign attesting to their awareness of the University's policies and procedures for the use of human subjects in research. Further, an ASPEN UNIVERSITY Professors/Faculty Chairs must sign illustrating that they have reviewed this application thoroughly and intend to oversee the research in its entirety and acknowledge their role as the principal investigator of record on their own behalf as well as on the behalf of the Doctoral Student.

5.1.1b. Proposal Narrative - The proposal narrative is a detailed description of the study. Each of the sections in the narrative needs to be completed, or if a section does not apply write "N/A." Each of these sections contains critical information that allows the reviewer to evaluate the study. These sections need to be written in lay language, avoiding jargon and acronyms. Failure to follow these rules causes delays in processing the submission. The responses to these questions allow the IRB to quickly place the study in the appropriate review category (exempt, expedited, or full review). These questions have been developed to decrease the response time of the IRB.

5.1.1c. Participant Letter - A letter inviting the human subject (s) to participant in the study must accompany the informed consent form.

5.1.1d. Informed Consent Form - An important component to any submission to the IRB committee is the informed consent form. This form is used by the researcher to document that the subject(s) were aware of the requirements of the study and that they were aware that they could refuse to participate or withdraw at any time up until publication of the project. Therefore, it is important that this document contain adequate information so that the subjects can make an informed decision regarding participation.

Note: Research involving deception will require additional justification and documentation related to informed consent processes.

Each of these components needs to be included in the package submitted to the IRB. Incomplete packages are returned to the principal investigator without review.

6. Review - Two copies of all materials should be sent to the IRB. Upon receipt of a protocol package the IRB reviews the package for completeness and content. If the package is found to be complete, the package is reviewed. If there are concerns or needed clarifications the IRB committee corresponds directly with the principal investigator to resolve these issues. The review process can take anywhere between 2 - 6 weeks, depending on the clarity and complexity of the proposal.

7. Final Notification - Upon receipt of the notification from the IRB reviewers of the acceptability of the experimental protocol, the IRB sends a letter to the principal investigator stating that the research project has been approved for one year (beginning on the date of the letter).

8. Extensions - For those projects that require an extension beyond the one-year limitation from the date of IRB approval, the principal investigator must submit a letter to the IRB stating their intention to continue the research and document any modification to the research protocol. The letter should also contain a concise updated overview of the project. Upon receipt of this letter, the IRB re-reviews the protocol and if it finds the protocol acceptable sends to the principal investigator a notice of extension.

9. Retention of Documentation - A copy of all records relating to the research project (original submitted protocol, all signed consent forms, correspondence with the IRB, etc.) should be safeguarded and retained for at least five years after the completion of the research. When destruction of records is necessary, the records must be disposed of by shredding or other permanent and safeguarded means of destruction.