Abraham Baldwin Agricultural College

INSTRUCTIONS FOR COMPLETING ABAC INSTITUTIONAL REVIEW BOARD APPLICATION FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

To initiate an Institutional Review Board (IRB) process, you will need to complete an application package. The package includes: 1) a standard form, using the instructions below. That form gives IRB members an overview of your project; 2) Completion certificates for a basic level of human subjects protection training available through Collaborative Institutional Training Initiative (CITI) for every person who will be collecting, viewing or treating research data from human subjects, including students; 3) A narrative in response to a series of questions about your project; 4) The consent, assent and/or permission forms you intend to use; 5) Copies of surveys, handouts, flyers or other material research subjects will see, use or respond to; 6) For projects involving unaffiliated investigators or for research projects taking place off campus, documentation of a working relationship with ABAC and permission from the outside institution. If you have any questions about how to apply, please contact Scott Pierce in the Office of Sponsored Programs.

Student Researchers:

- ❑ Complete the IRB Application for Use of Human Participants in Research form
- ❑ Attach descriptive and explanatory information as requested on the form, including samples of surveys, consent forms and FAQ to be used with project
- ❑ Attach valid certificate of human subjects research training through CITI for EACH student researcher
- ❑ Sign where indicated and
- ❑ Submit to supervising faculty

Faculty members supervising student researchers:

- ❑ Review the IRB Application for Use of Human Participants in Research and all submitted paperwork
- ❑ Complete the Faculty Advisor Routing Sheet
- ❑ Attach valid certificate of human subjects research training through CITI for EACH faculty member
- ❑ Sign where indicated and
- ❑ Submit all required documentation to the Office of Sponsored Programs

ABAC Faculty/Staff Researchers:

- ❑ Complete the IRB Application for Use of Human Participants in Research form
- ❑ Attach descriptive and explanatory information as requested on the form, including samples of surveys, consent forms and FAQ
- ❑ Attach valid certificate of human subjects research training through CITI for EACH investigator
- ❑ Sign where indicated and
- ❑ Submit all required documentation to the Office of Sponsored Programs

Unaffiliated Investigators:

- ❑ Complete the IRB Application for Use of Human Participants in Research form
- ❑ Attach descriptive and explanatory information as requested on the form
- ❑ Complete and attach Unaffiliated Investigator Agreement form
- ❑ Attach approval from Unaffiliated Investigator's IRB/institution of record

- ❑ Attach valid certificate of human subjects research training through CITI for EACH investigator
- ❑ Sign where indicated and
- ❑ Submit all required documentation to the Office of Sponsored Programs

Section I: researcher, mentor, and project information

Complete all applicable fields in this section. Incomplete forms will not be reviewed.

NOTE: If the research is or will be externally funded, include a copy of the portion of the proposal or award that describes use of human participants.

Section II: co-investigators/unaffiliated investigator information

ABAC undergraduate students involved in a group project should be listed in the co-investigator table, but do not have to indicate an FWA number.

NOTE: Unaffiliated investigators must fill out the last column, 'IRB FWA#", with the Federalwide Assurance number for the applying institution, then complete an Unaffiliated Investigator Agreement form. Contact the Office of Sponsored Programs for a copy of this form.

Section III: qualifying questions

Q1. Does your proposed study (a) meet the ABAC Institutional Review Board definition of research (as cited below) or (b) does it involve a condition for IRB oversight as listed below?

a) ABAC IRB Definition of Research: ABAC describes research as a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Generally, class projects and grant progress reports to funding agencies are not considered research. If the project or test results will be presented in any public forum, this does constitute research. Generally, institutional projects conducted solely for the purposes of internal evaluation are not considered research. If results are to be presented in any public forum, this does constitute research.

NOTE: Retroactive permission cannot be given under any circumstances.

b) Conditions: The following conditions may not meet the definition of "research" as provided above, but will cause your research to be subject to IRB oversight:
   i. Intent to produce results that will be submitted for peer-reviewed publication or presentation
   ii. Include minors (e.g., those under the age of 18)
   iii. Target potentially vulnerable individuals
   iv. May place pregnant women and/or fetuses at risk of physical harm
   v. Deal with a topic of sensitive nature in a way which anonymity cannot be sustained

vi. Involve any activity that places the participants at more than minimal risk (see Q8 for definition of "minimal risk")

Q2. Are the human participants in your study living individuals or are you collecting information about deceased persons that may put third parties (i.e., surviving spouses and/or living descendants) at more than minimal risk of harm? (See Q8 for definition of "minimal risk")

Q3. Will you obtain data through intervention or interaction with living or third-party individuals?

a) "Intervention" includes both physical procedures by which data are gathered (e.g., measurement of heart rate of venipuncture)
b) "Interaction" includes communication or interpersonal contact between the investigator and participant (e.g. surveying or interviewing)

Q4. Will you obtain identifiable private information about these individuals?
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. Identifiable means that the identity of the participant may be ascertained by the investigator.

a) Does your work involve human blood, body fluids, cells or tissue components?
b) Does your work involve recombinant DNA or a biohazard agent?

Q5. Does the primary researcher, co-investigator, or any other key person have a potential or actual significant financial conflict of interest in performance of the research? If yes, please complete the CITI module "Conflicts of Interest in Human Subjects Research" AND complete the ABAC Conflict of Interest form AND attach both to your application.

Q6. As a researcher you are expected to follow ABAC's code of ethics. Will there be any additional code of ethics followed? If yes, attach a copy of the relevant code.

Q7. Name and location of external organization(s) providing research participants (attach letter(s) of cooperation). Please visit our website for information and examples of the IRB's Model for a letter format for cooperating sites.

Q8. Does the study present more than minimal risk to the participants? "Minimal Risk" means that the risk of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk includes psychological, emotional, or behavioral risks to employability, economic well-being, social standing, and risk of civil criminal liability.

Q9. If the research project can be described by one or more of the categories listed below, please check all that apply (updated for 2018):

Category 1 — Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2 — Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)

Category 3 — Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording

Category 4 — Secondary research for which consent is not required

Category 5 — Research and demonstration projects that are conducted or supported by a federal department or agency

Category 6 — Taste and food quality evaluation and consumer acceptance studies

Category 7 – Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

Category 8 – Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use

Q10. Selection of Participants and Voluntariness: Describe (a) the participant population and any special characteristics of participants, (b) methods for selecting participants, and (c) procedures for assuring that their participation is voluntary. If utilizing data about human participants, describe the strategies you will employ to access data about the participants. Attach copies of flyers, posters, and/or letters that will be used to recruit participants, if applicable.

Q11. Informed Consent and/or Parental Permission/ Child Assent: Describe how you will implement the informed consent process. If English is not the participants' first language, describe how you will communicate with the participants and how you will provide an understandable written consent document. Attach a copy of the written informed consent and/or parental permission and child assent documents and/or provide any verbal or written explanation which will be given to the participant in lieu of a written informed consent document. If the consent process will be implemented in a foreign language, provide the foreign language script and documents as well as English versions. If appropriate, a Child Assent Form written at an age-appropriate level should also be developed.

Q12. Compensation: If participants will receive payment, extra-credit points, or any other form of compensation or special consideration for participation, state the form, amount, and conditions for award. Explain alternate activities and compensation that will be available to persons who elect to not participate in the research, if applicable.

Q13. Deception: If participants will be deceived, misled or if information will be deliberately withheld from participants as part of the study identify the information involved, justify the deception, and describe the debriefing plan. If deception will not be used, indicate such.

Q14. Research Protocol: In lay terms, briefly describe the specific procedures that relate to the participants' participation. What will the participants do and/or what will be done to them? Provide enough detail so that a lay reader will understand exactly what is going to occur in the study. Attach copies of all test instruments, questionnaires, and other data collection instruments that will be used. Describe how interviewers or data collectors will be trained. If appropriate, describe arrangements for referral of participants to support services or assistance that may be needed as a result of their participation in the research (e.g., referral for psychological counseling, medical treatment, etc.)

Q15. Privacy and Confidentiality: Explain if the participants will be identified and/or of their participation in the study might reasonably place them at risk for criminal or civil liability; or be damaging to their financial standing, employability, insurability, or reputation; or be stigmatizing. Describe the protections that will be implemented to reduce risks related to invasion of privacy and/or breach of confidentiality, including data collection, manipulation, and reporting methods to render the data anonymous/unidentifiable and/or disposal or destruction of participants' data or records.

NOTE: Federal and state regulations require the retention of human subjects research records for three years after completion of the final report. Research sponsors or the institution may impose a longer retention period that must be observed by the researcher. Thus, privacy protection should be assured until the end of the record retention period. Document destruction should also be discussed.

Q16. Risks: Describe all potential risks to the participants in the study, including potential physical, psychological, social, and/or economic harms. Discuss potential risks in relation to their probability and magnitude of harm. Explain the precautions that will be taken to minimize those risks.

NOTE: Rarely does participation in research carry no risk; the more appropriate statement is that risks are minimal or that there are no known risks associated with the research procedures. Please consider breach of confidentiality carefully given our increasingly online environment.

Q17. Benefits: Describe benefits likely to accrue to the participants. Describe the benefits of the proposed research to science and/or society in realistic terms. Remember, if there are no benefits but there are risks, your study is not likely to be approved.

Q18. Prior Research: If you have conducted prior research that bears on the risk-benefit ratio of this proposed study, please provide a brief summary of the methods and results. If you have not conducted such prior research, answer "Not Applicable".

Section V: Electronic signatures
The form uses Adobe Acrobat's e-signature functions. External subscriptions, such as AdobeSign, are not required. First, download the PDF file to your local computer. (Do not open it directly from Outlook.) Open in Adobe Acrobat. Click on the field where you need to sign and follow the automated instructions. If you have more than one electronic signature available (some people have external certifications they associate with Adobe), then select the one you want used. Click Continue. You will see a preview of your signature. Click Sign. You will be asked

to save a copy of the form locally. This version, the one that now has your signature on it, should go forward. You may always sign in ink, ask others to do so, scan as a PDF, then send forward for review.