Texas A&M University
Checklist
Protocol for Human Subjects in Research

The following is a checklist of the items you must provide to the IRB in order for them to approve your research. Please check and attach all items that apply to your research.

FOR ALL IRB APPLICATIONS: Attach the original and (1) one copy of the complete IRB Protocol. Submit your application to the Institutional Review Board, Office of Research Compliance, Sharon Aldere, Cenqe Building, 1500 Research Parkway, Suite B150, MS 1186. Applications requiring full review must be submitted a minimum of 15 working days before an IRB meeting depending on workload. Your protocol will be delayed if it is missing any of the required information. If you have any questions after reading the application you can call (979) 458-4067 for assistance. Allow sufficient time for protocol processing as it may take several months to obtain IRB Approval.

NOTICE: All submitted protocols require the following, when applicable.

- Part I: Summary Cover Sheet
- Part II: Detailed Study Description
- Part III: Conflict of Interest Statement
- Training Certificate(s) □ NIH Training Certificate □ TAMU RCR Certificate

Informed Consent Document (with all elements of consent)

- Consent Form
- Parental Permission Form
- Assent Form (if research involves minors, ages 7-17)
- Cover Letter for mail out surveys
- Information Sheet
- Telephone Script for telephone surveys
- Videotape/Audiotape Release Form (if not included in the consent and/or assent documents)
- Justification for Waiver of Consent or Signed Consent

Note: If consent or assent form is longer than one page, number each page in the format "page x of y" and blank space for date and initial "Date ____ Initial ____". Page #’s will be separate from IRB Application

- Debriefing form (if deception is used)
- Survey/Assessment Instruments
- Recruitment Media/Newspaper Advertisements
- Compensation conditions, schedule of payment
- FDA Form 1572 (for investigators involved in drug or biologic studies)
- Drug or Device Accountability Record

Email irb@tamu.edu or call (979) 458-4067 with any questions regarding this form.
Part I: Summary Cover Sheet

☐ Request for Exemption (Exempt from Full Board Review)
☐ Request for review under an Expedited Review Category
☐ Request for Full Review

New submission ☐  Re-submission ☐ (If protocol was disapproved)

Investigator Information
Principal Investigator Name: Amy Harder
Faculty ☐ Staff ☐ Graduate Student ☒ Undergraduate Student ☐
Department Agricultural Education  College COALS  Mail Stop 2116
Phone 979-458-2700  Email aharder@tamu.edu  Fax 979-458-2698

Is this study part of a Thesis or Dissertation? Yes ☐ No ☐
If Yes, do you have committee approval? Yes ☐ No ☐

Co-Principal Investigator Name:
Faculty ☐ Staff ☐ Graduate Student ☐ Undergraduate Student ☐
Department _____ College _____ Mail Stop _____
Phone _____ Email _____ Fax _____

Graduate Committee Chair/Faculty Advisor Name (if student): Gary Wingenbach
Department AGED  College COALS  Mail Stop 2116
Phone 979-862-1507  Email g-wingenbach@tamu.edu  Fax 979-458-2698

Project Title: Texas 4-H Agents’ Perceptions of Selected 4-H PRKC Competencies

Funding Status: Funded ☐ Not Funded ☒ Pending ☐ (Please attach a copy of Grant Proposal)
Funding Agency: _____  Funding Amount: _____
Funding Administrator: RF ☐ TAES ☐ TEES ☐ TAMU ☐ TTI ☐

Risk Management Matrix

<table>
<thead>
<tr>
<th>Seriousness of Risk</th>
<th>Probability That Something Will Go Wrong</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A (Likely to occur immediately or in a short period of time, expected to occur frequently)</td>
</tr>
<tr>
<td>I: May Result in Death</td>
<td>5</td>
</tr>
<tr>
<td>II: May cause severe injury, major damage or loss, and/or result in negative publicity for the participant(s) involved</td>
<td>5</td>
</tr>
<tr>
<td>III: Participation presents a minimal threat to safety, health and well-being of participant(s)</td>
<td>4</td>
</tr>
<tr>
<td>IV: No more than minimal risk</td>
<td>3</td>
</tr>
</tbody>
</table>

Red Zone – 4 thru 5  Yellow Zone – 2 thru 3  Green Zone – 1
(If your protocol falls in the Red or Yellow Zone, please call (979) 458-4067 for further instructions)

Seriousness of risk IV  Probability that something will go wrong 1
Objective Estimate of Risk to Subject:  Low ☐  Medium ☐  High ☒

<table>
<thead>
<tr>
<th>Activity</th>
<th>Associated Risks</th>
<th>Method to Manage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online Survey</td>
<td>None expected</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Will Existing Documents Be Used? Yes ☐ No ☒
Will Existing Specimens Be Used? Yes ☐ No ☒

Research Methodology: Qualitative ☐  Quantitative ☒  Both ☐

Gender of Subjects: Male ☐  Female ☐  Both ☒

Estimated Age of Subjects: 21-60

Location of Research: Texas A&M University

Total Participants: 93

Subject Recruitment
Subjects Recruited From:
☐ Psychology Subject Pool
☐ Other Subject Pool ☒
☐ Other TAMU Students
☐ Community
☐ Women/Fetuses
☐ Children
☐ Prisoners
☐ Hospitals
☐ Treatment Centers
☐ Schools
☐ Other Cooperative Extension

Compensation/Course Credit
Yes ☐  No ☒ Compensation for Subjects (If Yes, attach regular payment schedule)
Yes ☐  No ☒ Research/Course Credit for Subjects

Deception
Yes ☐  No ☒ Deception Used (If Yes, attach debriefing form)

Invasive or Sensitive Procedures
☒ None used
☐ Blood Samples
☐ Urine Samples
☐ Physical Measurements (electrodes, etc.)
☐ Stress Exercise
☐ Review of Medical/Psychological Records
☐ rDNA
☐ Other (specify): ____

Sensitive Subject Matter
☒ None used
☐ Abortion ☐  Sexual Activity
☐ AIDS/HIV ☐  Suicide
☐ Alcohol ☐  Learning Disability
☐ Body-composition ☐  Drugs
☐ Criminal-activity ☐  Depression
☐ Psychological Inventory
☐ Other (specify): ____

Audio or Video Taping
☐ Video Taping
☐ Audio Taping
If yes, answer the following:
Retained: Yes ☐  No ☒
Length of time retained: ____
Destroy/Erase: Yes ☐  No ☒
Other ____
Use specified in consent form: Yes ☒  No ☐

Provisions for Confidentiality/Anonymity
☒ Replies Coded
☐ Secure Storage
☐ Anonymous response OR
☒ Confidential
(Cannot be both anonymous and confidential)
Consent Documentation
☑ Consent Form    ☐ Parental Permission Form    ☐ Assent Form
☐ Cover Letter    ☑ Information Sheet    ☐ Telephone Script
☐ Videotape and/or Audiotape Release

Location where consent forms will be filed: Secured Computer Hard Drive in Scoates 218

Note: Consent forms must be kept on file for 3 years after completion of the study.

Request of waiver of consent: Yes ☐ No ☑ Request of waiver of signed consent: Yes ☐ No ☑
If yes to either, attach a justification for waiver request. Criteria for waiver requests can be found in the Federal regulation 45 CFR 46.116 and 45 CFR 46.117 at the following Web address: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

Do you have any relationship with any of the subjects, other than your investigator role? Yes ☐ No ☑
If yes, you must explain the relationship in Part II of the application and clarify how you will avoid any type of coercion (doctor-patient, teacher-student, counselor-student, etc.).

Other Compliance Issues
If the study involves the use of animals, infectious biohazards, and/or recombinant DNA, it is required that approval be granted for the use of such through the appropriate compliance committee. This information may be accessed through the Research Compliance Website at http://researchcompliance.tamu.edu.

This study also involves the use of animals. ☐Yes ☑ No
If yes, complete the following:
☐ An application has been submitted for review by the University Lab Animal Care Committee.
☐ An application has been reviewed and approved by the University Lab Animal Care Committee.
AUP Number: _____ Approval Date: _____

This study also involves the use of infectious biohazards or recombinant DNA. ☐Yes ☑ No
If yes, complete the following:
☐ A registration form has been submitted for review by the Institutional Biosafety Committee.
☐ An approved registration is currently on file with the Institutional Biosafety Committee.
Registration Number: _____ Approval Date: _____

Abstract
Please provide a brief statement, in lay terminology, outlining the purpose of this study. (Why you are doing this research project and what you propose to learn.)

This research project is being conducted to explore the perceptions that 4-H Extension agents have of selected competencies listed in the 4-H Professional Research, Knowledge, and Competency model. Participants will be asked to assess their level of proficiency in the selected competencies, as well as each competency's importance. The results will be used to assess the professional development needs of 4-H agents in Texas.

The U.S. population is becoming increasingly culturally, linguistically, economically, and ethnically diverse. The research needs to make a concerted effort to ensure that research subjects reflect the population demographically, including these groups who have been traditionally under represented. However, it is recognized that the available pool of subjects may preclude having a balanced population. If you cannot use a diverse population in your research, you must justify this action in Part II, A, 1.

For answers to questions regarding the IRB application process, please check with the IRB office at (979) 458-4067 or irb@tamu.edu. All protocol applications require an original and one (1) copy of each instrument, i.e., protocol checklist, Part I, Part II (with signatures), Part III, consent documents, research instrument(s), recruitment materials, training certificates, etc.
REQUEST FOR EXEMPTION (from full IRB review)

45 CFR 46.101(b) - Some research projects involving human subjects are exempt from full review by the IRB. The IRB makes the final decision whether or not a proposal is exempt from full IRB review. If the protocol cannot be reviewed under and exempt category, it will be placed on the next available IRB meeting agenda. (Sensitive topics and subjects such as children or minors, pregnant women and prisoners are not considered for exempt research).

Basis for Exemption (Do not check unless requesting an exemption from full IRB review.)

☐ 45 CFR 46.101(b)(1) - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
☒ 45 CFR 46.101(b)(2) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
☐ 45 CFR 46.101(b)(3) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☐ 45 CFR 46.101(b)(4) - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
☐ 45 CFR 46.101(b)(5) - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
☐ 45 CFR 46.101(b)(6) - Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

REQUEST FOR EXPEDITED REVIEW UNDER THE FOLLOWING CATEGORIES

45 CFR 46.110 - Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. The IRB makes the final decision whether or not a proposal may be expedited. If the protocol cannot be reviewed under an expedited category, it will be placed on the next available IRB meeting agenda.

Expedited Review Adjunct Categories (Do not check unless requesting expedited review)

☐ 1. Clinical studies of drug and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
Part II: Detailed Study Description

Part A – Protocol Information

1. Selection of Subjects
   a. Source and number: 93 4-H Extension agents in Texas
   b. Method of recruitment and selection: E-mail; census of agents in Texas with "4-H Youth Development" as part of their professional title. Agents will self-select to participate by following a link to the information sheet and entering a password to access the online questionnaire.
   c. Ages and gender: 21 - 60 Male and Female
   d. Compensation: None
   e. Location and duration of experiment: Online; 20 minutes
   f. Specific steps to ensure confidentiality or anonymity of responses of results: Confidential; responses are coded and retained through secure transmission and storage protocols.
   g. The investigator’s relationship to subjects: None

2. Purpose of study: This research project is being conducted to explore the perceptions that 4-H Extension agents have of selected competencies listed in the 4-H Professional Research, Knowledge, and Competency model. Participants will be asked to assess their level of proficiency in the selected competencies, as well as each competency’s importance. The results will be used to assess the professional development needs of 4-H agents in Texas.

   a. Physical/Behavioral Aspects: Participants will be e-mailed an invitation to participate in the study, as well as the information sheet. Those who are willing to participate can choose to follow a link to the survey. Agents will self-select to participate by entering a password to access the questionnaire, which has 59 close-ended questions. Participants can skip any question or exit at any time.
   b. Deception or Coercion: None

4. Risks and Benefits to Subjects
   a. A description of any potential risks or discomforts to the subject: No risks or discomforts are anticipated from this research. Participants who do not wish to be involved can choose not to answer the questions or may exit the questionnaire at any time, without penalty.
   b. A definition of benefits to the research subject or alternatives for participation in the study. Note: Do not include broad benefits to society or potential research benefits to a group as a benefit to the subjects. Participant responses may be used to revise/adjust professional development opportunities for 4-H Extension agents.
Part B – Signature Assurance

*Principal Investigator/Graduate Student Assurance Statement

I understand Texas A & M University’s policy concerning research involving human subjects and I certify that:

1. I have read The Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” and subscribe to the principles it contains. In light of this Declaration, I present for the Board’s consideration this application, which will be explained to the subject about the proposed research.
2. I accept responsibility for the scientific and ethical conduct of this research study;
3. I will obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form:
4. I will immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;
5. I will complete, on request by the IRB, the Continuation/Final Review Forms.

SIGNATURE: _________________________________________ DATE: 9/14/06

TYPED NAME: Amy Harder E-MAIL: aharder@tamu.edu

Co-PI SIGNATURE: _________________________________________ DATE: ______

TYPED NAME: _______ E-MAIL: _______

*Faculty/Research Advisor’s Assurance Statement

I certify that I have read and agree with this proposal, that the PI has received adequate training to perform this research, and will receive adequate supervision while performing this research.

SIGNATURE: _________________________________________ DATE: 9/14/06

TYPED NAME: Gary Wingenbach E-MAIL: g-wingenbach@tamu.edu

* All investigators must have the signature from the department head for completion of the signature assurance. Undergraduate and graduate students must have faculty/research advisor’s signature in addition to the signature of the department head.

**Department Head

This is to certify that I have reviewed this research protocol and agree that the research activity is within the mission of the Department and appropriate for the responsibilities and assigned duties of the principal investigator.

SIGNATURE: _________________________________________ DATE: 9/14/06

TYPED NAME: Christine Townsend E-MAIL: ctownsend@tamu.edu

**If the principal investigator is also the Department Head, the College Dean or equivalent must sign the Signature Assurance Sheet.
Part III: Conflict of Interest Statement

Please check or provide details on the following information (enter N/A if not applicable)

Principal Investigator Name: Amy Harder

Department: Agricultural Education  College: COALS

Phone 979-458-2700  Email aharder@tamu.edu  Fax 979-458-2698  Mail Stop 2116

Project Title: Texas 4-H Agents' Perceptions of Selected 4-H PRKC Competencies

Funding Agency: N/A

Funding Administrator: RF  TAES  TEES  TAMU  TTI

☑ I have no conflict of interest related to this project.

☐ I have a non-financial conflict of interest related to this project. (If checked, please describe below.)

☐ I have a financial conflict of interest related to this project. (If checked, please provide information regarding the financial interest as described below and as it applies to this project. All items must be marked confidential and provided in a separate envelope or folder.)

a) The names of affected corporations, both for-profit and not-for-profit, for which the person serves as a member of the governing board in the capacity of a director, advisory director, trustee, or otherwise.
b) The names of affected corporations for which the person serves as an executive officer.
c) The name of affected partnerships, limited partnerships, proprietorships, or other business associations of which the person is a partner, joint venture or owner.
d) The amount of any compensation received for services related to (a), (b), (c), including any benefits, direct or indirect (reported by range of amounts), and benefits received for intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
e) Affected business entities in which the person holds a controlling interest or is the principal shareholder.
f) Whether the person is employed by any affected business entities described in (a) through (e) above that have any relationship to Texas A&M University or any of its components, and a brief description of such relationship.

_____________________________________________________ ______________________
Signature of Investigator      Date

(Original signature only – a “per” signature is not acceptable)

Note: This disclosure must be updated annually as the IRB protocol 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 forfeit IRB approval and possible funding. Co-investigators must also complete a conflict of interest statement and submit with all paperwork.