Application for Review of Human Subjects Research

Questions and completed forms should be submitted to the UAFS Institutional Review Board, IRB@uafs.edu.
This form must be typed. Handwritten applications will not be accepted. Any incomplete forms will be returned to the researcher.

Date of Submission to IRB: _____

Project Title: _____

Checklist for Application Submission

☐ **Application Form** (follows on pages 2-11 of this packet)

☐ **Required Appendices** — All appendices should be labeled accordingly in the file naming convention. If a pdf is submitted, bookmarks should be used to separate appendices from the application.

- ☐ **Appendix A: Consent Form(s)**
  - ☐ Informed Consent Form
  - ☐ Parental Permission (Assent) Form (if any participants are under age 18)
- ☐ **Appendix B: Recruitment**
  - ☐ Scripts used to verbally invite participants to participate in the study
    and/or
  - ☐ Copies of flyers, announcements, email, text, or other written forms of recruitment
- ☐ **Appendix C: Instrument(s)** [e.g. questionnaire, survey, testing, pictures/documents presented to participants, etc.]
- ☐ **Appendix D: Human Ethics Research Training Verification**
  - ☐ for PI (principal investigator)
  - ☐ for PIs advisor (if PI is a student)
  - ☐ for all co-PIs

  Note: UAFS IRB does not maintain certifications on file. PIs who have done past research with the UAFS IRB should resubmit their certifications. All named PIs must have certifications. Students may pursue certification at no cost through the UAFS Blackboard Training by emailing Lisa Norris, IRB chair.
- ☐ **Appendix E: Letters of Permission (if needed)**
- ☐ **Appendix F: Grant Proposal (if funded project)**

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Submit electronically to IRB@uafs.edu.

Project Title: _____

Suggested Level of Review

I believe this research study fits the criteria for the following level of review:

☐ **Exempt by Category Number** _____

Go here to view descriptions of exempt research category numbers d-1 through d-8. You MUST fill in a category number in the blank above. Note: Research can be approved as "exempt" if it is no more than "minimal risk" and fits one of the exempt review categories as defined by federal regulation 45 CFR 46. Studies that may quality for "exempt" must still be submitted to the IRB for review.

☐ (d)(1)
☐ (d)(2) Which criteria are met? ☐ (i) ☐ (ii) ☐ (iii)
☐ (d)(3)(i) Which criteria are met? ☐ (A) ☐ (B) ☐ (C)(ii) ☐ (C)(iii)
☐ (d)(4) Which criteria are met? ☐ (i) ☐ (ii) ☐ (iii) ☐ (iv)
☐ (d)(5)(i) or ☐ (d)(5)(ii)
☐ (d)(6) Which criteria are met? ☐ (i) ☐ (ii)
☐ (d)(7)
☐ (d)(8) (i-iii)

☐ **Expedited by Category Number** _____

Go here to view descriptions of expedited research category numbers 1-9. You **MUST** fill in a category number in the blank above.

☐ 1(a) or ☐ 1(b)
☐ 2(a) or ☐ 2(b)
☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7
☐ 8(a)) or ☐ 8(b) or ☐ 8(c)
☐ (9)

☐ **Full Board** — Describe precise risks necessitating full review status:

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Section 1: Researcher Information

Principal Investigator Information

The principal investigator (PI) is responsible for the direction and conduct of the research activities during the project. The PI is also responsible for selecting and supervising project staff and all requirements necessary to maintain compliance with applicable institutional and/or sponsor/funder rules and regulations.

PI Name: _____ **PI Email:** _____

PI College and Department: _____

PI Office Address: _____ **PI Telephone:** _____

IF PI is a student

Advisor Name: _____ **Advisor Email:** _____

Advisor College and Department: _____

Advisor Office Address: _____ **Advisor Telephone:** _____

Co-PI Information

The co-PI is a senior member of the research team whose role is similar to the PI. However, the co-PI defers to the PI as the individual with ultimate responsibility for the conduct of the research project. The co-PI is obligated to ensure the project is conducted in compliance with applicable institutional and/or sponsor/funder rules and regulations.

Co-PI Name: _____ **Co-PI Email:** _____

Co-PI College and Department: _____

Co-PI Office Address: _____ **Co-PI Telephone:** _____

Co-PI Name: _____ **Co-PI Email:** _____

Co-PI College and Department: _____

Co-PI Office Address: _____ **Co-PI Telephone:** _____

If there are more than two co-PIs for this project, please provide the information requested above for all PIs.

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Other Research Personnel

Other research personnel are individuals who have a role on the research project (e.g., interacting with participants, assisting with data collection and/or analysis) but are not responsible for the research project as a whole. This could include people such as student Research Assistants.

If your project has Other Research Personnel, please list these individuals either by name OR by position title. If there are none, leave this section blank.

Human Subject Research Assurance:

☐ I, as the PI, understand that all other research personnel must complete Human Subject Research training before they work on the project. I will ensure all other research personnel will complete this training before working on the project and will keep record of it.

Conflict of Interest

Do you, the PI, or any other responsible personnel (or the spouse and/or dependent children thereof) have financial interests related to this study?

☐ No ☐ Yes

If yes, please explain.

Do you, the PI, the co-PI, or any other research personnel (of the spouse and/or dependent children thereof) have responsibilities as an employee or leader at the research site?

☐ No ☐ Yes

If yes, please explain.

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Section 2: Problem, Purpose, and Research Questions

Briefly (100 words or less) describe the purpose of the proposed study.
Include all research questions, hypothesis, and/or evaluation questions. Include a brief summary of related information from the published literature on this topic in a language understandable to someone who is not familiar with your area of study. Your response in this section will enable the reviewers to determine whether the project meets the criteria of research with human participants and also the extent to which the research may produce new generalizable knowledge that may benefit the participants and/or society.

How will the results of this project be used? (Check all that apply.)

☐ Presentation ☐ Publication ☐ Thesis ☐ Dissertation

☐ Other (please specify):

Section 3: Participants, Sampling, and Recruitment Information

Describe the target participants of this study.

Within the population of potential participants, are there any criteria that would exclude someone from qualifying as a participant in your study?

☐ No ☐ Yes

If yes, please explain.

Are there any participants in this study under 18 years of age?

☐ No ☐ Yes

If yes, please describe how you will comply with special regulations for having children as participants in research studies.

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Check all descriptors that apply to the target sample for this study.
Note: Only check boxes for those you intend to purposefully include in the study. "Healthy Adults" covers general adult samples where other categories/demographics are not being specifically/purposefully studied.

- ☐ Healthy Adults
- ☐ Children Under 18
- ☐ Pregnant Women/Fetus
- ☐ Prisoners/Felons
- ☐ Institutionalized Person(s)
- ☐ Ward(s) of the State
- ☐ LGBTQ person(s)
- ☐ Native Americans
- ☐ Older Adults (65+)
- ☐ Economically Disadvantaged
- ☐ Educationally Disadvantaged
- ☐ Physical Disabilities
- ☐ Employees and/or Supervisors
- ☐ Students in Your Class/School
- ☐ Internet Methodologies
- ☐ Live in a Foreign Country
- ☐ Limited Literacy
- ☐ Undocumented
- ☐ Gender-Specified Research
- ☐ Race/Ethnic Minority-Specific Research
- ☐ Community Engaged and/or Participatory Research
- ☐ Person(s) with Intellectual Disabilities
- ☐ Specific Health Conditions and/or End of Life
- ☐ Students in Elementary/Secondary Schools

☐ Other (please specify):

Please select all the tools you plan to use to recruit participants.

- ☐ Flyers
- ☐ Mailers
- ☐ Email
- ☐ Presentation at Meeting
- ☐ Notices/News Releases
- ☐ Online Advertisements
- ☐ Social Media
- ☐ Personal Contacts
- ☐ Snowball Methods
- ☐ Research Management Software (e.g., SONA)
- ☐ TV, Radio, or Print Advertising
- ☐ Asked Verbally/Face-to-Face by Researcher
- ☐ Asked Verbally/Face-to-Face by Designee (specify designee)

☐ Other (please describe):

Describe, step by step and in layman's terms, the actual procedures to be used to recruit participants.
Elaborate on any considerations needed for special populations. If participants will be contacted more than once, explain when follow up recruitment will happen (Example: two weeks after the first email). Include copies of scripts, flyers, advertisements, posters, or letters (including follow-up/reminders) to be used in Appendix B.

Approximate number of subjects expected to participate:

Expected duration of participation for each participants:
This includes the actual length of time they will be observed/tested/questioned. (Example: "It will take 30 minutes to fill out consent form and questionnaire." If there is more than one session/data collection period, please specify the duration of each session. (Example: "It will take 30 minutes for pre-test and 30 minutes for post-test, and the two tests will occur eight weeks apart".)

Describe any follow-up recruiting procedures planned.
(Example: If you intend to contact participants after an intervention/at a future date (e.g., post-tests))

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Section 4: Data Collection Procedures

Will any existing data sets be accessed for information for this study?

☐ No ☐ Yes

If yes, please describe the existing data set, how it will be accessed by the researcher and what identifiable information will be included in the data set.

Which of the following will data collection involve? Check all that apply.

Attach permission letters and/or letters of support in Appendix E of this application if needed.

☐ Educational Tests (cognitive, diagnostic, aptitude)
☐ Biological Specimen(s)
☐ Photographs and/or Artifacts
☐ Interview Procedures - In Person
☐ Focus Group Procedures - In Person
☐ Survey(s)/Questionnaire(s) - Paper
☐ Observation - Participatory
☐ Audio Recording
☐ Self-Health Monitoring
☐ Food Consumption Procedures
☐ Psychological Tests
☐ Use of Social Networking Sites
☐ Anthropomorphic Measures
☐ Interview Procedures - Phone/Online
☐ Focus Group Procedures - Phone/Online
☐ Survey(s)/Questionnaire(s) - Phone/Online
☐ Observation - Non-Participatory
☐ Video Recording
☐ Electronic Devices
☐ Educational Records/Materials
☐ Research in/with P-12 Schools/Students
☐ Experimental Presentation Software (e.g., Python, E-Prime, Psychopy, etc.)
☐ Community-Engaged or Community-Based Participatory Research Procedures

☐ Other (please specify):

Provide a detailed description of data collection methods, procedures, interventions, or manipulations of human subjects or their environments.

Include copies of any questionnaires, tests, written instruments, instructions, scripts, etc. in Appendix C . If you are using an electronic device to collect data, describe how the electronic device works. Note: In this context an electronic device is not survey software such QuestionPro or Survey Monkey.

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Describe the location where the research will take place (e.g., online, physical location, etc.).
Attach permission letters and/or letters of support with your application.

Describe the calendar time frame for gathering the data using human subjects.
This should include approximate dates of data collection. PLEASE NOTE THE IRB CANNOT UNDER ANY CIRCUMSTANCES RETROACTIVELY APPROVE A RESEARCH PROPOSAL. Your initial dates of contacting participants must be AFTER IRB approval.

Will any incentives be offered to the participants for their participation?
NOTE: If course credit or extra credit is offered, describe the alternative means for obtaining credit available to those students who do not wish to participate in the research project (whether the alternative is offered by the researcher or instructor of the course).

☐ No ☐ Yes

If yes, please explain.

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Section 5: Risks and Benefits

From the list below, please select all the potential risks that are involved in this proposed study.

- ☐ Social or economic risks (e.g., reputation, employability, cultural, etc.
- ☐ Breach of privacy of subject or subject's family members
- ☐ Injury or bodily harm
- ☐ Identification of illegal activity
- ☐ Identification of child, spousal, or elder abuse
- ☐ Presentation of materials which may be considered sensitive, offensive, threatening, or degrading
- ☐ Probing for personal or sensitive information in surveys or interviews (e.g., private behaviors, employer assessments, etc.)
- ☐ Manipulation of psychological or social state such as sensory deprivation, social isolation, or psychological stress
- ☐ Use of private records (e.g., educational or medical records
- ☐ Use of deceptive techniques, including incomplete disclosure

- ☐ Other risks (please specify):

☐ For participants in this study, there are no risks of any kind that are greater than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.

Describe the nature and degree of risk or harm selected above.
All risks/harms must be disclosed in the consent form Appendix A. If using deception, please justify its use and describe how participants will be debriefed afterwards.

Describe the steps that will be taken to minimize risks and/or harms and protect the welfare of the subjects.
Include a description of how you will handle an adverse or unexpected outcome (e.g., referral to counseling services). If the study includes protected populations, identify each group and provide an explanation for how risks/harms will be minimized and handled for each group.

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Will medical clearance be necessary for subjects to participate because of tissue sampling, administration of substances (such as food or drugs), or physical exercise conditioning?

All risks/harms must be disclosed in the consent form in Appendix A. If using deception, please justify its use and describe how participants will be debriefed afterwards.

☐ No ☐ Yes

If yes, please explain how clearance will be obtained.

What are the costs to participants?

This can include money, time (such as time to fill out questionnaires), etc. You should also consider the "cost" of participation in the study such as transportation, time off work, etc.

Describe the benefits that individuals may reasonably expect from participants. If there are none, please state "None."

Describe the anticipated benefit of this study to society, academic knowledge, or both.

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Section 6: Privacy and Confidentiality

Data in this study will be collected:

☐ Anonymously with no direct or indirect coding, link, or awareness of who participated in the study (including no collection of IP addresses for electronic methods)

☐ Confidentially, but with a link of subjects' data to any identifying information (collected confidential, but recorded and analyzed as anonymous)

☐ Confidentially with collection and protection of linkages to identifiable information

Will you or any member of your research team collect or have access to any of the following personal identifiers? (Select all that apply.)

☐ Name
☐ Phone or Fax Numbers
☐ License, Certificate, or Other IDs
☐ Signatures or Handwriting Samples
☐ Date of Birth
☐ Social Security Number
☐ IP Address
☐ Photos/Images
☐ Mailing or Email Address
☐ Student ID
☐ Biometric Identifiers
☐ Audio or Video Recording

☐ Other (please specify):

☐ No member of the research team will have access to any personal identifiers.

Describe why each identifier you are collecting is necessary/required for this study.

Describe how and where the data/personally identifying information will be stored and secured, including the type(s) of device(s) used to store the information.

Who will have access to the identifiers?

Identify people by name or position title and specify their relationship to the research. Describe how you will ensure that non-authorized personnel do not have access to the identifier data.

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What will be done with the identifiers and/or any master keys/lists that link names to subject numbers after the study is completed? How will identifiers be removed? When is the latest date that identifying information or links will be retained?

Describe the steps you are taking to protect the confidentiality of the participants and how you are going to advise participants of these protections in the consent process.

Note: For focus groups, confidentiality may not be maintained because other participants are in the focus group itself. If your study includes focus groups, we recommend using the following language in the consent form (Appendix A) and in the verbal directions given during the focus group itself: The researcher(s) will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, since one of the elements of this study is a focus group, other people in the focus group will be aware of what is shared in the group. Each individual in the focus group is asked not to share the discussions of the group outside of the group, but the researcher(s) cannot guarantee confidentiality in that setting.

What confidentiality or security measures/precautions will be used to protect (or not collect) identifiable data? Include protections used during the collection, transfer, and storage of data.

Where will data be stored and secured?

How long do you intend to keep raw data and how will it be destroyed after that time period?
Note: Federal regulations require raw data (and any coding/identifier key sheets) to be kept for at least three (3) years. Typically, raw data is shredded or erased within five (5) years, particularly if identifiers are attached. Anonymous data can be kept forever.

Will participation in this study be made part of any record available to a participant's supervisor, teacher, or employer?

☐ No ☐ Yes

If yes, please describe.

Will tissue samples or specimens be collected?

☐ No ☐ Yes

If yes, when will they be destroyed?

Will they be used for research other than what is described in the consent?

☐ No ☐ Yes

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Section 7: Consent Procedures

Describe, step by step, the procedures to be used to obtain the consent/assent of participants.
Include the context, how, when, and how often (for multiple-phase studies) consent will be sought and who will be responsible for seeking consent. If there are any possible communication barriers involved (e.g., non-English speaking participants; physically disabled, blind, or hearing-impaired participants; participants with cognitive impairments or delays), explain in detail how these will be addressed. Provide copies of all consent documents (and parental permission (assent) documents if needed) in Appendix A.

Are you requesting a Waiver of Documentation of Consent (i.e., no signature on the consent/assent forms)?
If you are conducting an online survey or an anonymous survey (online or in paper form), check yes.

☐ No ☐ Yes

If yes, what is the justification for the waiver?

☐ The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

☐ The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

☐ Other (please specify): (Example: The study is mixed methods with one part online and one part in person.)

Are you requesting to waive:

1. some elements of consent/assent or parental permission? ☐ No ☐ Yes

OR

2. the entire consent/assent or parental permission (assent) process? ☐ No ☐ Yes

If yes to either or both, provide how you will make sure ALL of the following criteria are met:

1. The research involves no more than minimal risk to the subjects.

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

How will you make it clear to the participants that their participation is voluntary and they may withdraw from the study at any time they wish without penalty?

Typically, this is stated in the consent (Appendix A). However, there may be situations where it is explained more than once. Cut and paste the relevant statement here.