***In completing the following application, please present the request in TYPEWRITTEN form and in nontechnical terms, where applicable. Also, please do not delete any sections of the application.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Click or tap to enter a date. |  | **Initial  Continuing** |  |  |
| **Date Submitted** |  | **Type of Submission** |  | **Protocol Number (*IRB Use Only*)** |

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| --- |
| Click or tap here to enter text. |

**Title of Research Project (if funded, provide exact title of funded project)**

**PRINCIPAL INVESTIGATOR (PI)**

|  |  |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |

**Name College Department/External Institution or Agency**

|  |  |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |

**Email Address Phone Extension/Number**

**CO-PRINCIPAL INVESTIGATOR (CO-PI), *if applicable***

|  |  |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |

**Name College Department/External Institution or Agency**

|  |  |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |

**Email Address Phone Extension/Number**

**CO-INVESTIGATOR (CO-I), *if applicable***

|  |  |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |

**Name College Department/External Institution or Agency**

|  |  |
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| Click or tap here to enter text. | Click or tap here to enter text. |

**Email Address Phone Extension/Number**

***► If there are multiple Co-Principal Investigators/Investigators, please list them in the Research Personnel form. All additional research personnel must also be listed on the Research Personnel form and attached with your submission.***

|  |  |
| --- | --- |
| **Anticipated Funding Source, *if applicable*:** | Click or tap here to enter text. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Projected Duration of Research (months/years):** | Click or tap here to enter text. |  | **Projected**  **Start Date:** | Click or tap to enter a date. |

|  |  |
| --- | --- |
| **Other organizations and/or agencies involved in the study, *if applicable*:** | Click or tap here to enter text. |

**Is this a collaborative or multi-site study?**  Yes  No

**If Yes, will AWC be the IRB of Record for the participating sites?**  Yes  No

**If AWC will Not be the IRB of Record, who will be the IRB of Record for the participating sites?** Click or tap here to enter text.

**Does the research require a Single IRB for review? (*The AWC IRB is currently not equipped to serve as the IRB of record.)***  Yes  No

**Is this project strictly a review of data or specimens? (*No recruitment, interaction, or consent*.)**  Yes  No

**LOCATION OF RESEARCH**

Arizona Western College, list campuses: Click or tap here to enter text.

External Institution, list institutions: Click or tap here to enter text.

Online

Other, list locations: Click or tap here to enter text.

**PROJECT ABSTRACT**

**Background:** Provide the scientific or scholarly background for the proposed Human Research. Discuss relevant prior experience or preliminary data (e.g., existing literature).

|  |
| --- |
| Click or tap here to enter text. |

**Purpose:** Describe the purpose, specific aims, objectives, questions to be answered, hypotheses, and/or primary and secondary study endpoints of the Human Research.

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| --- |
| Click or tap here to enter text. |

**Summary:** Provide a brief description of the proposed research using terms that someone who is not familiar with the science or your discipline can understand.

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| --- |
| Click or tap here to enter text. |

**Resources:** Describe the resources (personnel, facilities, time, emergency resources, etc.) available to recruit, consent, conduct study procedures, and analyze data.

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| Click or tap here to enter text. |

**POPULATION & RECRUITMENT**

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| --- |
| Click or tap here to enter text. |

**Maximum number of participants to be enrolled in the study:**

**Select categories of participants that will be included in the research (select all that apply):**

|  |  |
| --- | --- |
| Children (1-17 years old) | Prisoners |
| Cognitively Impaired Subjects | Refugees |
| Adults (18 years or older) | AWC Staff/Faculty |
| Native Americans | AWC Students |
| Pregnant Woman/Neonates (0-2 years old) | Other – please explain: Click or tap here to enter text. |
|  |

**What are the inclusion and exclusion criteria for study participation?**

|  |
| --- |
| Click or tap here to enter text. |

**Indicate age range, gender, and ethnicity of your research population:**

|  |
| --- |
| Click or tap here to enter text. |

**Select the methods that will be used to recruit individuals (select all that apply). *Attach copies of documents, as applicable*:**

|  |  |
| --- | --- |
| Email | Social Media |
| Flyers | Online Advertisements |
| TV, Radio, Print | Phone Calls |
| Face-to-Face | In Person Presentations |
| Other – please explain: Click or tap here to enter text. |

**Explain the recruitment process:**

|  |
| --- |
| Click or tap here to enter text. |

**Where will recruitment take place?**

|  |
| --- |
| Click or tap here to enter text. |

**When will recruitment occur? *Provide a time frame with dates if applicable.***

|  |
| --- |
| Click or tap here to enter text. |

**INFORMED CONSENT**

**Indicate the informed consent process(es) and/or document(s) to be used in the study (select all that apply). *Attached copies of documents, as applicable*.**

|  |  |
| --- | --- |
| Informed Consent – written form | Informed Consent – oral script, online, or unsigned |
| Assent (participants under 18) – written form | Assent (participants under 18) – oral script, online, or unsigned |
| Parental Permission – written form | Parental Permission – oral script, online, or unsigned |
| Translated Consent/Assent – written form(s) | Translated Consent/Assent – oral script, online, or unsigned |
| Waivers of Consent | Exception from Informed Consent |
| Short Consent – written form | Other – please explain: Click or tap here to enter text. |
| Debriefing Script |

**Describe in detail the consent process(es) checked above, including any waiting period for subjects to sign the consent, steps to minimize the possibility of coercion or undue influence, and the language used by those obtaining consent.**

|  |
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| Click or tap here to enter text. |

**DATA COLLECTION PROCEDURES**

**Select the methods of data collection that will be employed in this study (select all that apply):**

|  |  |
| --- | --- |
| Audio/Video Recording | Anthropometric Measures (e.g. height, weight, waist circumference, etc.) |
| Benign Interventions | Data previously collected for research purposes |
| Cognitive or behavioral measures, including daily diaries (note: if surveys will also be administered, please select the appropriate option above) | Data collected using other communication/electronic devices (e.g., cell phones, pagers, and texting devices) |
| Interviews – In person | Deception |
| Interviews – Focus groups | Surveys – Internet (including online and email-based data collection) |
| Participant Observation | Non-invasive instruments (e.g., external sensors applied to the body) |
| Self-health monitoring (e.g., pedometers, food diaries, etc.) | Screening Data |
| Surveys – Paper | Randomization with Control and Experimental Groups |
| Surveys – Telephone | Records – Educational |
| Use of Social Networking Sites | Records – Billing |
| Records – Employee | Other Activities/Interventions – please explain: |
|  |

**Provide details of the research procedures, including a description of procedures already being performed on subject for diagnostic or treatment purposes. Be clear to identify which procedures are specifically for research, and which study population will be completing each study procedure.**

|  |
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| Click or tap here to enter text. |

**Please state the estimated time commitment for subject participation.**

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| Click or tap here to enter text. |

**BENEFITS, COSTS, COMPENSATION, & RISKS**

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

|  |
| --- |
| Click or tap here to enter text. |

**Describe any benefits that individuals may reasonably expect from participation.**

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| --- |
| Click or tap here to enter text. |

**Describe any costs, monetary and non-monetary, that subjects may incur. (Note: Time is considered a cost.)**

|  |
| --- |
| Click or tap here to enter text. |

**Discuss the amount of compensation (monetary and/or non-monetary) subjects may receive. Describe if compensation will be prorated.**

|  |
| --- |
| Click or tap here to enter text. |

**Describe all physical, psychological, social, legal, and/or economic risk you feel are associated with participation in this research. (*Note: Risks not directly related to the research need not be included in this section.*)**

|  |
| --- |
| Click or tap here to enter text. |

**Discuss what steps have been taken to minimize risk to subjects/data.**

|  |
| --- |
| Click or tap here to enter text. |

**PRIVACY and CONFIDENTIALITY**

**Will the research team be accessing education records, or employee records during the research?**  Yes  No

**Please identify where data will be stored (select all that apply):**

|  |  |
| --- | --- |
| Password Protected Drive | Encrypted Drive |
| External Drive (USB, Flash drive) | Department Drive |
| Cloud Server | Other – please explain: Click or tap here to enter text. |
| Departmental Office |
|  |

**For each of the storage locations checked above, discuss the type of data to be stored (including if the data is identifiable), who may have access to the data, and how long the data will be kept. (Note: You are responsible for following institutional policy and procedures for proper transmission and storage of Confidential or Regulated data, including Protected Health Information.)**

|  |
| --- |
| Click or tap here to enter text. |

**Will you be transmitting to/receiving from an outside group any subject data?**

Yes No

**Discuss how, when and why subjects/data may be removed from the study. If abrupt withdrawal is necessary, discuss how subjects will be withdrawn so that they are not put at increased risk. Discuss what happens if a subject is withdrawn from one part of the study but asked to continue with other parts, such as ongoing follow-up.**

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| Click or tap here to enter text. |

**Describe steps, if any, to protect the privacy of the subjects throughout their participation in the Human Research (e.g., during the recruitment process, consent process, and/or research procedures).**

|  |
| --- |
| Click or tap here to enter text. |

**USE OF DATA/SPECIMENS**

**In which of the following formats will the data be stored?**

Identifiable  Coded  De-Identified

**What security controls (e.g., administrative, physical, technical) are in place to make sure data/specimens are secure?**

|  |
| --- |
| Click or tap here to enter text. |

**Will subjects receive, results for any future research?** Yes No

**Will the data be stored in a repository?** Yes No

**Will the data be shared with collaborating entities?** Yes No

**Provide a brief discussion of the plan to monitor for subject safety, if applicable. Describe what safety information will be collected, including serious adverse events, how safety information will be collected, the frequency of collection including a timeline of when the data and review(s) will occur, who will review the information, and the plan for reporting finding. If there will not be a way to monitor for subject safety, please explain.**

|  |
| --- |
| Click or tap here to enter text. |

**DEPARTMENTAL REVIEW & APPROVAL (*if applicable*)**

**By signing below, I, the Department Head, certify that I have reviewed this application and determined that all departmental requirements are met and that the investigator(s) has/have adequate resources to conduct the Human Research.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Click or tap here to enter text. |  |  |  | Click or tap to enter a date. |
| Department Head Name & Title |  | Department Head Signature |  | Date |

*Please Note: Actual signature is not required. The IRB will accept either email confirmation or an actual signature. This means that all signatures might not be on the same document. Attach email confirmations with your submission, if applicable.*

**FACULTY ADVISOR/MENTOR (*if applicable*)**

**Research proposals by undergraduate or graduate students must have the following attestation statement signed by a Faculty Advisor or Mentor.**

**By signing below, I, the Faculty Advisor/Mentor, certify that I have accurately reviewed and mentored the student regarding completion of the Human Research Application.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Click or tap here to enter text. |  | |  | |  | | Click or tap to enter a date. | |
| Faculty Advisor/Mentor Name | |  | | Faculty Advisor/Mentor Signature | |  | | Date |

*Please Note: Actual signature is not required. The IRB will accept either email confirmation or an actual signature. This means that all signatures might not be on the same document. Attach email confirmations with your submission, if applicable.*

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR AND RESEARCH STAFF**

* Protect the rights and welfare of human subjects who participate in research.
* Understand the ethical standards and regulatory requirements governing research activities with human subjects.
* Personally conduct or supervise the research.
* Ensure that all staff, collaborators, and colleagues assisting in the conduct of the study are informed about the study, regulations governing research, and institutional policies.
* Ensure that all research activities have IRB approval and other approvals required by the institution before human subjects are involved.
* Implement the research activity as it was approved by the IRB.
* Obtain the informed consent of subjects before they are involved in the research and document consent as approved by the IRB.
* Maintain written records of IRB reviews and decisions.
* Obtain and keep documented evidence of informed consent of the subjects (or their legally authorized representatives).
* Obtain IRB approval for any proposed change to the research plan prior to its implementation.
* Comply with the IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.
* Make provisions for the secured retention of complete research records and all research materials.
* Ensure the confidentiality and security of all information obtained from and about human subjects.
* Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other organizations.
* Notify the IRB of any relevant new information that may impact the safety/security of subjects’ health or privacy.

The PI is responsible for retaining informed consent documents for a period of three years after the project.

Though research responsibility may be delegated to research staff, PIs must maintain oversight and retain ultimate responsibility for the conduct of those to who they delegate responsibility.

**Principal Investigator (PI):**

**I, the Principal Investigator, certify that the protocol and method of obtaining informed consent as approved by the Arizona Western College Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.**

**By signing below, I certify that the information I provided in this application is correct and complete.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Click or tap here to enter text. |  |  |  | Click or tap to enter a date. |
| Principal Investigator Name (typed) |  | Principal Investigator Signature |  | Date |

**Co-Principal Investigator (Co-PI):**

**I, the Co-Principal Investigator, certify that the protocol and method of obtaining informed consent as approved by the Arizona Western College Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.**

**By signing below, I certify that the information I provided in this application is correct and complete.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Click or tap here to enter text. |  |  |  | Click or tap to enter a date. |
| Co-Principal Investigator Name (typed) |  | Co-Principal Investigator Signature |  | Date |

**Co-Investigator (Co-I):**

**I certify that the information I provided in this application is correct and complete.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Click or tap here to enter text. |  |  |  | Click or tap to enter a date. |
| Co-Investigator Name (typed) |  | Co- Investigator Signature |  | Date |

***Please attach the following documentation to your completed Human Research Application, as applicable:***

* PI/Co-PI CV or Biosketch
* List of Project Personnel
* Copies of Completed CITI Training Certificate for All Project Personnel listed
* Appendices (if applicable)
* Recruitment Material(s)
* Informed Consent Documentation
* Data Collection Tools
* Email confirmation from Faculty Advisor (required for all students)
* Email confirmation from Department Head

***You have now completed the Human Research Application.***

***Next Steps:***

1. ***Save a copy of this document for your records***
2. ***Once ready, email the application and all additional documents and approvals to IERG@azwestern.edu***
3. ***The Office of Institutional Effectiveness and Research will notify you of the IRB Determination of your complete Human Research Application within 10 working days.***

***Please limit your submission to one email whenever possible.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AWC IRB DETERMINATION OF HUMAN RESEARCH**  ***(IRB Use Only)*** | | | | |
| ***IRB Chair/Designated IRB Member – Check 1 box below*** | | | | |
| **EXEMPT**  ***Select Exemption Category:***  **1  2  3  4  5  6**  ***AWC is not implementing broad consent at this time therefore, categories 7 & 8 are not applicable.*** | | **EXEMPT w/Limited IRB Review**  ***Select Exemption Category:***  **1  2  3  4  5  6**  ***AWC is not implementing broad consent at this time therefore, categories 7 & 8 are not applicable.*** | | |
| **APPROVED – Expedited Review**  ***Select Expedited Category:***  **5  6  7  8  9**  ***Categories 1-4 are not applicable as they primarily pertain to biomedical research studies.*** | | **APPROVED – Expedited Review with Conditions**  ***Select Expedited Category:***  **5  6  7  8  9**  ***Categories 1-4 are not applicable as they primarily pertain to biomedical research studies.*** | | |
| **APPROVED – Full Board Review** | | **APPROVED – Full Board Review with Conditions** | | |
| **DEFERRED** | **TABLED** | | **DISAPPROVED** | |
| **NOT RESEARCH** | | **NOT HUMAN SUBJECTS RESEARCH** | | |
| **Signature of IRB Committee Chair/Designated IRB Member:** | | | | **Date:** Click or tap to enter a date. |