Alabama College of Osteopathic Medicine

Protocol Approval Request

for Research Involving Human Participants for review by the Institutional Review Board

Part 1: Administrative Information

1. Title of protocol

2. Contact information

2.1. Principal Investigator (PI) - *Please See College Policy

Name

Email address

Division

Status ☐ Student ☐ Faculty ☐ Staff ☐ Other

2.2. Co-PIs and members of the research team:

Name	Email	ACOM/non ACOM	Division	Organization (not in ACOM)	Address (if not ACOM)

3. Funding information

3.1. Indicate if your project is funded by an external (non-ACOM) sponsor, including a gift or a sponsored award.

- ☐ Federal Funding Agency:
- ☐ Federal Flow through funds
- ☐ Student projects funded fully or in part by Federal funds received by a Faculty Advisor
- ☐ Non Federal sponsor that requires compliance with Federal IRB regulations
- ☐ Other Funding source
- ☐ My research is not funded by any outside funding agency
  (This option should be available only if none of the above are selected)

Name of the external funding agency:

Provide the Sponsor's Project ID number:

Part 2: Study Design, Methods and Procedures

1. Type of project/study: Please select ALL of the categories of work that apply to this proposed project.

- ☐ Active collection of data (not human biological materials or physiological data)
- ☐ Active collection and use of human biological materials or physiological data
- ☐ Use of physiological or biomedical devices, or drugs, biologics, or chemical agents
- ☐ Use of existing data (not human biological materials)
- ☐ Use of existing human biological materials

2. **Please provide a lay summary of the study, including the purpose, research questions and hypothesis to be evaluated.**

3. **Please describe briefly how this study will contribute to existing knowledge in the field.**

Part 3: Participants, Recruitment and Compensation

1. **Please provide the estimated number of participants you plan to recruit and how this number is signifigant (please see "How to Determine Signifigance if needed")**

2. **Please provide the age range of the participants.**

3. **Please select all the categories of participants that will be included in your study.**

- ☐ Healthy adult volunteers
- ☐ Children under 18
- ☐ Employees of the investigating group
- ☐ Students
- ☐ Employees
- ☐ Cognitively impaired persons
- ☐ Pregnant or nursing women
- ☐ Prisoners or individuals under detention or on probation
- ☐ People in foreign countries
- ☐ People unable to read, speak or understand English
- ☐ Healthy adult volunteers

- [ ] People with specific health conditions
- [ ] Other category of participants not listed above

Please explain below:

- [ ] None of the above

4. **Please select all of the tools that you plan to use to recruit your participants.**

- [ ] Flyers
- [ ] Notices
- [ ] Mailers (U.S. Post)
- [ ] Online
- [ ] Advertisements
- [ ] Email
- [ ] Use of Internet social media or online networking sites TV, radio, print advertisements
- [ ] Face to face or going into the public to obtain participants
- [ ] Presentations at meetings Other (Please describe below)

5. **Please describe each recruitment method to be used.**

6. **Describe the inclusion or exclusion criteria for participants as applicable in this study.**

7. **Will participants be compensated for their participation?** ☐ Yes ☐ No

8. **Please describe the tasks that the participants will be asked to perform for each phase of the study.**

9. **Please provide an estimate of the time commitment from each participant for each phase of the study.**

Part 4: Risks and Benefits

1. **From the list below, please select ALL of the known and potential risks that are involved in your study.**

- ☐ Use of deceptive techniques
- ☐ Use of private or confedential records (such as educational or medical records)
- ☐ Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress
- ☐ Probing for personal or sensitive information in surveys or interviews (e.g.: private behaviors, employer assessments)
- ☐ Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading
- ☐ Possible invasion of privacy of subject or subject's family
- ☐ Social or economic risk (reputational, cultural, employability, etc.)
- ☐ Identification of child, spousal, or elder abuse
- ☐ Identification of illegal activity Risk of injury or bodily harm
- ☐ Other risks (please specify)

☐ There are no risks of any kind to any participants enrolled in this study. *This option is valid only if none of the risks above are selected.*

2. **Describe the nature and degree of the risks or harms selected above. All of the risks/harms must be disclosed in the consent form.**

3. **Describe the steps that will be taken to minimize risks or harms and to protect the welfare of participants. Include a description of how you will handle an adverse or unexpected outcome that could be potentially harmful (e.g., suicidal ideation). If the study will include protected populations, identify each group and provide an explanatory paragraph for each group.**

4. **Describe any benefits that individuals may reasonably expect from participation. If there are none, state "None."**

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

Part 5: Privacy and Confidentiality

1. **Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.**

☐ Name
☐ Date of birth

☐ Mailing or email address
☐ Phone or fax numbers
☐ Social Security number
☐ Medical records
☐ License, certificate or Vehicle
☐ ID IP address
☐ Biometric identifiers
☐ Photos/images/audio
☐ recording Signatures,
☐ handwriting samples
☐ Any unique identifier not mentioned above:
☐ No member of the research team will have access to any personal identifiers. *This option is valid only if none of the other options in this question are selected.*

Part 6: Consent Process

Please refer to the Consent Form Template

1. Informed Consent:

1.1. Will you use a written informed consent document?

☐ Yes

☐ No, I am seeking a waiver of written informed consent

☐ Not applicable

2. Written assent for individuals under 18:

2.1. Will you obtain written assent for children and individuals under 18?

☐ Yes

☐ No, I am requesting a waiver of written assent

☐ Not applicable

3. Written parental permission:

3.1 Will you obtain written parental or guardian permission for children and individuals under 18?

☐ Yes

☐ No, I am requesting a waiver of written parental or guardian permission

☐ Not applicable

Part 7: Financial Conflict of Interest Disclosure

ACOM requires that personnel conducting research involving human participants must disclose known significant financial interests that would reasonably appear to be affected by the research project and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict be managed prior to their engagement in the research with human participants. Significant financial interests include:

- An equity interest in an external entity that, when aggregated for the investigator and the investigator's spouse/same sex partner and dependent children over the past 12 months and expected over the next 12months exceeds $5,000 in value, or represents more than 5% ownership interest.
- Salary, royalties, or other payments from an external entity that, when aggregated for the investigator, the investigator's spouse/same sex partner and dependent children over the past 12 months and expected over the next 12 months are expected to exceed $5,000.

1. **Have all faculty listed on this protocol (including faculty supervisor)** completed the Annual Disclosure for your external commitments and financial interests

   ☐ Yes ☐ No

2. **Have all faculty listed on this protocol (including faculty supervisor)** disclosed all significant financial interests (as described above) that are reasonably related to this research project?

   ☐ Yes ☐ No

3. **For all personnel listed on this protocol:** Do any of the personnel, their spouses or dependent children have any significant financial interests that are reasonably related to this research?

   ☐ Yes ☐ No

4. **For all personnel listed on this protocol:** Do any of the personnel, their spouses/same sex partners, or dependent children have any personal financial interest or commitment with any company or entity that sponsors or supports this research? ☐ Yes ☐ No

If you answered "Yes" to either #3 or #4, please contact Human Protections Administrator for guidance on next steps regarding disclosure, review of the financial interest and resolution of any real or apparent conflict of interest. The IRB is not able to review this project until it has been determined by the Human Subjects Administrator that no

investigator involved in this research activity has a conflict of interest related to this research.

Reminder Check List

You have now completed this form. Please review it to ensure that it is filled out completely and accurately. Please save this form and proceed to the signature page for submission instructions. If you have any questions or need assistance, please contact the Human Protections Administrator.

Phone: 334-944-4022

Email: tbryan@acomedu.org

Signature

This page is to be signed by the principal investigator. If the principal investigator is a student, the faculty supervisor must also sign in the lower box.

OPTIONAL: You may submit an electronic copy of this application. After clicking on the attestation box, please save a copy of the form before emailing it to tbryan@acomedu.org.

Principal Investigator

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board for Human Participants.

☐ Attestation of Principal Investigator

_____ _____

Name / Signature of Principal Investigator Date