**AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS**

**PROTOCOL REVIEW FORM
FULL BOARD or EXPEDITED REVIEW**
For assistance, contact: **The Office of Research Compliance (ORC)**Phone: **334-844-5966** E-Mail: **IRBAdmin@auburn.edu** Web Address: [**http://www.auburn.edu/research/vpr/ohs**](http://www.auburn.edu/research/vpr/ohs) **Submit completed form and supporting materials as one PDF through the** [**IRB Submission Page**](https://aub.ie/irbsubmission)Form must be populated using Adobe Acrobat / Pro 9 or greater standalone program (do not fill out in browser). Handwritten forms are not accepted.
Where links are found hold down the control button (Ctrl) then click the link.

1. Proposed Start Date of Study:Click or tap to enter a date.Today’s Date:Click or tap to enter a date.Submission Status (Check One): [ ]  New [ ]  Revisions(to address IRB Review Comments)
 Proposed Review Category (Check One): [ ]  Full Board (greater than minimal risk) [ ]  Expedited
 If Expedited, Indicate Category(ies) (([Link to Expedited Category Review Sheet](https://cws.auburn.edu/OVPR/pm/compliance/irb/guidance)) Click or tap to enter category.

2. Project Title: Click or tap here to enter text.

3. Principal Investigator (PI): Click or tap here to enter text. Degree(s): Click or tap here to enter text.
 Rank/Title: Choose Rank/Title Department/School: Choose Department/School
 Role/responsibilities in this project: Click or tap here to enter text.
 Preferred Phone Number: Click or tap here to enter text. AU Email: Click or tap here to enter text.

 Faculty Advisor Principal Investigator (if applicable):Click or tap here to enter text. Rank/Title:Choose Rank/Title Department/School:Choose Department/School Role/responsibilities in this project:Click or tap here to enter text.Preferred Phone Number:Click or tap here to enter text. AU Email: Click or tap here to enter text.Department Head:Click or tap here to enter text.Department/School:Choose Department/School Preferred Phone Number:Click or tap here to enter text.AU Email: Click or tap here to enter text.Role/responsibilities in this project: Click or tap here to enter text.

4. Funding Support: [ ]  N/A [ ]  Internal External Agency: Click or tap here to enter text. Pending [ ]  Received [ ]
 For federal funding, list funding agency and grant number (if available): Click or tap here to enter text.

5. a) List any contractors, sub-contractors, other entities associated with this project: Click or tap here to enter text.

 b) List any other AU IRB approved protocols associated with this study and describe the association: Click or tap here to enter text.

 c) List any other institutions associated with this study and submit a copy of their IRB approvals: Click or tap here to enter text.

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| **Protocol Packet Checklist** |
| **Check all applicable boxes. A completed checklist is required.**[ ]  **Protocol Review Form** (All required signatures included and all sections completed) (Examples of appended documents are found on the website: <https://cws.auburn.edu/OVPR/pm/compliance/irb/sampledocs>)[ ]  **CITI Training Certificates** for key personnel[ ]  **Consent Form or Information Letter** and any releases (audio, video or photo) that participants will review and/or sign[ ]  **Appendix A** “Reference List”[ ]  **Appendix B** if e-mails, flyers, advertisements, social media posts, generalized announcements or scripts, etc., will be used to recruit participants.[ ]  **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Attach  documents in the order they are listed in item 13c. **Continued on Page 2**[ ]  **Appendix D** if they study will use a debriefing form or will include emergency plans/ procedures and medical referral lists. (A referral list may be attached to the consent document.)[ ]  **Appendix E** if research is being conducted at sites other than Auburn University or in cooperation with other entities. A **permission letter** from  the site/ program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi- site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of **IRB  approval** from each entity is required prior to initiating the project.[ ]  **Appendix F** Written evidence of approval by the host country, local IRB or institutions if research is conducted outside the United States |

 **6. General Research Project Characteristics**

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| **6A. Research Methodology** |
| **Check all descriptions that best apply to the research methodology.** |
| **Data Source(s):**  [ ]  New Data [ ]  Existing Data | **Will recorded data directly or indirectly identify participants?** [ ]  Yes [ ]  No |
| **Data collection will involve the use of:** [ ]  Educational Tests (cognitive diagnostic, aptitude, etc.) [ ]  Internet / Electronic  [ ]  Interview [ ]  Audio [ ]  Observation [ ]  Video [ ]  Locations or Tracking Measures [ ]  Photos [ ]  Physical / Physiological Measures or Specimens (see section 6E) [ ]  Digital Images[ ]  Surveys / Questionnaires [ ]  Private records or files [ ]  Other: Click or tap here to enter text. |
| **6B. Participant Information** | **6C. Risks to Participants** |
| **Check all descriptors that apply to the TARGET population. (link to** [**definition of target population**](https://cws.auburn.edu/OVPR/pm/compliance/irb/guidance)**)** [ ]  Males [ ]  Females [ ]  AU students**Vulnerable Populations**[ ]  Pregnant Women/Fetuses [ ]  Prisoners [ ]  Institutionalized[ ]  Children and / or Adolescents (under age 18 in AL)**Persons with:**[ ]  Economic Disadvantages [ ]  Physical Disabilities[ ]  Educational Disadvantages [ ]  Intellectual Disabilities**Will participants be compensated?** [ ]  Yes [ ]  No | **Identify all risks participants might encounter in this research.**[ ]  Breach of Confidentiality\* [ ]  Coercion[ ]  Deception [ ]  Physical[ ]  Psychological [ ]  Social[ ]  None[ ]  Other (COVID-19, other medical): Click or tap here to enter text.\*Note that if the investigator is using or accessing confidential or identifiable data, reach of confidentiality is always a risk. |
| **D. Corresponding Approval/ Oversight** |
| * **Does the study include participant exposure to radiation?** [ ]  **Yes** [x]  **No**

**If yes indicate:** [ ]  **DEXA** [ ]  **PQCT** [ ]  **Other*** **Is IBC Approval required for this study?**[ ]  **Yes** [ ]  **No**

**If yes, BUA #** Click or tap here to enter text. **Expiration Date**  Click or tap to enter a date.* **Is IACUC Approval required for this study?**[ ]  **Yes** [ ]  **NoIf yes, PRN #** Click or tap here to enter text. **Expiration Date**  Click or tap to enter a date.
* **Does this study involve the Auburn University MRI Center?**[ ]  **Yes** [ ]  **No Which MRI(s) will be used for this project? (Check all that apply)**

[ ]  **3T** [ ]  **7T** **Continued on Page 3****Does any portion of this project require review by the MRI Safety Advisory Council?**[ ]  **Yes** [ ]  **NoSignature of one MRI Center Representative:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*****Required for all projects involving the AU MRI Center*****Appropriate MRI Center Representatives:** **Dr. Thomas S. Denney, Director AU MRI Center** **Dr. Ron Beyers, MR Safety Officer** |

**7. Project Assurances**

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| **7A. Principal Investigator’s Assurances** |

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical
 performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any
 stipulations imposed by the Auburn University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and
 responsibilities and are in compliance with Auburn University policies regarding the collection and analysis of the
 research data.
4. I agree to comply with all Auburn policies and procedures, as well as with all applicable federal, state, and local laws
 regarding the protection of human subjects, including, but not limited to the following:
 a. Conducting the project by qualified personnel according to the approved protocol
 b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of
 Research Compliance
 c. Obtaining the legally effective informed consent from each participant or their legally responsible representative
 prior to their participation in this project using only the currently approved, stamped consent form
 d. Promptly reporting significant adverse events and / or effects to the Office of Research Compliance in writing
 within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct
 responsibility in my absence. This person has not been named as co-investigator in this application, or I will advise
 ORC, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Auburn University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Research Compliance
 before the approval period has expired if it is necessary to continue the research project beyond the time period
 approved by the Auburn University IRB.
8. I will prepare and submit a final report upon completion of this research project.

My signature indicates I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

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**Principal Investigator Name Principal Investigator Signature Date**

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| **7B. Faculty Advisor / Sponsor’s Assurances** |

1. I have read the protocol submitted for this project for content, clarity, and methodology.
2. By my signature as faculty advisor / sponsor on this research application, I certify that the student or guest investigator
 is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training
 and experience to conduct this particular study in accord with the approved protocol.
3. I agree to meet with the investigator on a regular basis to monitor study progress. Should problems arise during the
 course of the study, I agree to be available, personally, to supervise the investigator in solving them.
4. I assure that the investigator will promptly report significant incidents and / or adverse events and / or effects to the
 ORC in writing within 5 working days of the occurrence.
5. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I
 will advise the ORC by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of
 renewals, modifications or the final report, I will assume that responsibility.

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**Faculty Advisor / Sponsor Name Faculty Advisor Signature Date**

 **Continued on Page 4**

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| **7C. Department Head’s Assurance** |

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all Auburn University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department
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 **Department Head Name Department Head Signature Date**

**8. Project Overview:**

**8A. A summary of relevant research findings leading to this research proposal:**
 *(Cite source; include a “Reference List” as* ***Appendix A****.)* Click or tap here to enter text.

**8B. A brief summary/abstract of the study methodology, including design, population, and variables of interest.
 (**350 word maximum, in language understandable to someone who is not familiar with your area of study):Click or tap here to enter text.

**9. Purpose**

**9A. State the purpose of the study and all research questions or aims.** Click or tap here to enter text.

**9B. Describe how results of this study will be used? (e.g., presentation? publication? thesis? dissertation?)** Click or tap here to enter text.

**10. Key Personnel.** Describe responsibilities as specifically as possible. Include information on research training or certifications related to this project. **To** **determine key personnel see decision tree at** [**https://cws.auburn.edu/OVPR/pm/compliance/irb/training**](https://cws.auburn.edu/OVPR/pm/compliance/irb/training)**.** **Submit a copy of CITI training documentation for all key personnel.** (For additional personnel, add lines as needed).

To determine Auburn University HIPAA – covered entities click link to [HIPAA Policy](https://sites.auburn.edu/admin/universitypolicies/Policies/HIPAAHybridEntityPolicy.pdf).

If any key personnel have a formal association with institutions/entities involved in the study (for example is an employee or supervisor at the site research will occur), describe that affiliation. For all non-AU affiliated key personnel, submit a copy of their IRB approval.

**Principal Investigator:** Click or tap here to enter text. **Title:** Choose Rank/Title **Email Address:** Click or tap here to enter text.
**Dept / Affiliation:**  Choose Department/School H**IPAA Covered Entity? Yes** [ ]  **No** [ ]
**Roles / Responsibilities:** Click or tap here to enter text.- Do you have any known competing financial interests, personal relationships, or other interests that could have
 influence or appear to have influence on the work conducted in this project? [ ]  Yes [ ]  No
- If yes, briefly describe the potential or real conflict of interest:Click or tap here to enter text.

**Individual:** Click or tap here to enter text. **Title:** Choose Rank/Title **Email Address:** Click or tap here to enter text.
**Dept. / Affiliation:** Choose Department/School **HIPAA Covered Entity? Yes** [ ]  **No** [ ]
**Roles / Responsibilities:** Click or tap here to enter text.
- Do you have any known competing financial interests, personal relationships, or other interests that could have
 influence or appear to have influence on the work conducted in this project? [ ]  Yes [ ]  No
- If yes, briefly describe the potential or real conflict of interest:Click or tap here to enter text.

**Individual:** Click or tap here to enter text. **Title:** Choose Rank/Title **Email Address:** Click or tap here to enter text.
**Dept. / Affiliation:** Choose Department/School **HIPAA Covered Entity? Yes** [ ]  **No** [ ]
**Roles / Responsibilities:** Click or tap here to enter text.- Do you have any known competing financial interests, personal relationships, or other interests that could have
 influence or appear to have influence on the work conducted in this project? [ ]  Yes [ ]  No
- If yes, briefly describe the potential or real conflict of interest:Click or tap here to enter text.

**Individual:** Click or tap here to enter text. **Title:** Choose Rank/Title **Email Address:** Click or tap here to enter text.
**Dept. / Affiliation:** Choose Department/School **HIPAA Covered Entity? Yes** [ ]  **No** [ ]
**Roles / Responsibilities:** Click or tap here to enter text.- Do you have any known competing financial interests, personal relationships, or other interests that could have
 influence or appear to have influence on the work conducted in this project? [ ]  Yes [ ]  No
- If yes, briefly describe the potential or real conflict of interest:Click or tap here to enter text.

**Individual:** Click or tap here to enter text. **Title:** Choose Rank/Title **Email Address:** Click or tap here to enter text.
**Dept. / Affiliation:** Choose Department/School **HIPAA Covered Entity? Yes** [ ]  **No** [ ]
**Roles / Responsibilities:** Click or tap here to enter text.- Do you have any known competing financial interests, personal relationships, or other interests that could have
 influence or appear to have influence on the work conducted in this project? [ ]  Yes [ ]  No
- If yes, briefly describe the potential or real conflict of interest:Click or tap here to enter text.

**11.** **Location of research.**

**11A. List all locations where data collection will occur.** Attach permission letters as Appendix E.(School systems,
 organizations, businesses, buildings and room numbers, servers for web surveys, etc.) **Be as specific as possible.**
 (See sample letters at <https://cws.auburn.edu/OVPR/pm/compliance/irb/sampledocs>)Click or tap here to enter text.

**11B. Will study data be stored within a HIPAA covered facility? Yes** [ ]  **No** [ ]  **If yes, which facility(ies)** (To determine AU HIPPA covered entities, go to VII of the [HIPPA Hybrid Entity Policy](https://sites.auburn.edu/admin/universitypolicies/Policies/HIPAAHybridEntityPolicy.pdf))**:** Click or tap here to enter text.

 **12. Participants**

**12A. Describe the targeted/ intended participant population for the study including the number of
 participants and inclusion and exclusion criteria for participant selection.**

[ ]  **Check here if existing data will be used and describe the population from whom data was collected
 including the number of data files.**

[ ]  **Check here if permission to access existing data is required and submit a copy of the agreement to
 access.**

Click or tap here to enter text. **12B. Describe, step-by-step in lay language all procedures to recruit participants.** Include in **Appendix B**
 a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to
 participate. (See sample documents at <https://cws.auburn.edu/OVPR/pm/compliance/irb/sampledocs>)

 Click or tap here to enter text.

**12C. Minimum number of participants required to validate the study?** Click or tap here to enter text.

 **Number of participants expected to enroll?** Click or tap here to enter text.

 **Is there a limit to the number of participants that will be included in the study?** [ ]  **No** [ ]  **Yes, the number** **is** Click or tap here to enter text.

**12D.** **Describe the process to compensate, amount and method of compensation and/or incentives for**

 **participants.** [**AU Procurement and Business Services (PBS) policies**](https://sites.auburn.edu/admin/universitypolicies/Policies/PolicyonHumanParticipantIncentives.pdf)

(benefits to participants are NOT compensation)

If participants will not be compensated, check here: [ ]  Indicate the amount of compensation per procedure and in total: Click or tap here to enter text.

 Indicate the type of compensation: [ ]  Monetary [ ]  Incentives
 [ ]  Raffle or Drawing incentive (Include the chances of
 winning.)
 [ ]  Extra Credit (State the value)
 [ ]  Other

 Describe how compensation will be distributed (USPS, email, etc.): Click or tap here to enter text.

**13. Project Design & Methods**

**13A. Describe, step-by-step, all procedures and methods that will be used to consent participants. If a
 waiver is being requested, indicate the waiver, and describe how the study meets the criteria for
 the waiver. If minors will be enrolled describe the process to obtain parental/ legally authorized
 guardian permission.**

[ ]  **Waiver of Consent (including using existing data)** [ ]  **Waiver of Documentation of Consent (use of Information Letter)** [ ]  **Waiver of Parental Permission (for college students 18 years or younger)**

Click or tap here to enter text.

**13B. In lay language, understandable by someone not familiar with the area of study, describe the
 complete research design and methods that will be used to address the purpose. Include a clear
 description of who, when, where and how data will be collected.** Include specific information about
 participants’ time and effort.

 Click or tap here to enter text.

**13C. List all data collection instruments used in this project, in the order they appear in Appendix C.**
 (e.g., surveys and questionnaires in the format that will be presented to participants, educational tests, data
 collection sheets, interview questions, audio/video taping methods etc.)

 Click or tap here to enter text.

**13D. Data analysis: Describe how data will be analyzed.**

Click or tap here to enter text.

**13E. List any drugs, medications, supplements, or imaging agents that participants will ingest/ receive**

 **during participation in the study or indicate not applicable (N/A).**

Click or tap here to enter text.

**14. Risks & Discomforts: List and describe all the risks participants may encounter in this research including
 risks from item 6d of this form, in this research. If deception will be part of the study, provide the rationale
 for the deception, describe the debriefing process, and attach a copy of the debriefing form that will be used**

 **as Appendix D.** (Examples of possible risks are in section #6C)

Click or tap here to enter text.

**15. Precautions / Minimization of Risks**

**15A.** Identify and describe all precautions that will be taken to eliminate or reduce risks listed in items 6.c. and 14. If
 participants can be classified as a “vulnerable” population, describe additional safeguards that will be used to assure
 the ethical treatment of vulnerable individuals. **If applicable, submit a copy of any emergency plans/procedures
 and medical referral lists in Appendix D. (Sample documents can be found online at** <https://cws.auburn.edu/OVPR/pm/compliance/irb/sampledocs> **precautions)**

Click or tap here to enter text.

**15B. If the internet, mobile apps, or other electronic means will be used to collect data, describe confidentiality
 and/or security precautions that will be used to protect (or not collect) identifiable data? Include protections
 used during collection of data, transfer of data, and storage of data. If participant data may be obtained
 and/or stored by apps during the study, describe.**

Click or tap here to enter text.

**15C. Additional Safeguards
 Will DEXA, pQCT, or other devices which emit radiation be used?** [ ]  **Yes** [ ]  **No**

 **If yes, the IRB will notify the Auburn Department of Risk Management and Safety, who will contact the**

 **Alabama Department of Public Health (ADPH) and secure approval.** **Research which includes device(s)**

 **which emit radiation may NOT be initiated NOR will IRB stamped consent documents be issued until the**

 **IRB is notified of ADPH approval.**

* **Will a Certificate of Confidentiality (CoC) issued by NIH be obtained** [ ]  **Yes** [ ]  **No If yes, include CoC
language in consent documents and include the documentation of CoC approval. Research which includes a CoC may not be initiated NOR will IRB stamped consent documents be issued until the IRB is notified of CoC approval.** [**AU Required CoC Language**](https://cws.auburn.edu/OVPR/pm/compliance/irb/guidance)
* **Is the study a** [**clinical trial**](https://cws.auburn.edu/OVPR/pm/compliance/irb/guidance)**?** [ ]  **Yes** [ ]  **No
 If yes, provide the National Clinical Trial (NCT) #** Click or tap here to enter text. **and include required clinical
 trial information in all consent documents.** [**AU Clinical Trial Information**](https://cws.auburn.edu/OVPR/pm/compliance/irb/guidance)

**16. Benefits**

**16A. List all realistic direct benefits participants can expect by participating in this study.** (Compensation is not a
 benefit) If participants will not directly benefit check here. [ ]

 Click or tap here to enter text.

**16B.** **List realistic benefits for the general population that may be generated from this study.**

Click or tap here to enter text.

**17. Protection of Data**

**17A. Data are collected:**

[ ]  **Anonymously with no direct or indirect coding, link, or awareness by key personnel of who participated
 in the study (skip to item E)**

[ ]  **Confidentially, but without a link to participant’s data to any identifying information (collected as
 “confidential” but recorded and analyzed “anonymous”) (Skip to item E).**

[ ]  **Confidentially with collection and protection of linkages to identifiable information.**

**17B. If data are collected with identifiers and coded or as coded or linked to identifying information,
 describe the identifiers and how identifiers are linked to participants’ data.**

Click or tap here to enter text.

 **17C. Provide the rationale for need to code participants’ data or link the data with identifying
 information.**

Click or tap here to enter text.

**17D. Describe how and where identifying data and/or code lists will be stored.** (Building, room number,
 AU BOX?) **Describe how the location where data is stored will be secured. For electronic data,
 describe security measures. If applicable, describe where IRB-approved and participant signed
 consent documents will be kept on campus for 3 years after the study ends.**

Click or tap here to enter text.

**17E. Describe how and where data will be stored (e.g., hard copy, audio/ visual files, electronic data,
 etc.), and how the location where data is stored is separated from identifying data and will be
 secured. For electronic data, describe security. Note use of a flash drive or portable hard drive is
 not appropriate if identifiable data will be stored; rather, identifying participant data must be
 stored on secured servers.**

Click or tap here to enter text.

**17F. List the names of all who will have access to participants’ data?** (If a student PI, the faculty advisor

 must have full access and be able to produce study data in the case of a federal or institutional audit.)

 Click or tap here to enter text.

**17G.****When is the latest date that identifying information or links will be retained and how will that
 information or links be destroyed?** (Check here if only anonymous data will be retained [ ] )

 Click or tap here to enter text.

**Version Date:** Click or tap to enter a date.