Alabama College of Osteopathic Medicine

Human Research Protection
Exempt Application Checklist
IRB-1F

Applicant(s) Name:

Project Name:

Please answer the following questions about your research protocol to determine if your study can be considered for exempt review. Once completed, submit to research administration office.

If you answer yes to any of the questions below, your study will not qualify as exempt research and you must complete an application for either expedited or full review.

	Question	Yes	No
For research involving special populations, interventions, or manipulations:			
1	Does your research involve prisoners?		
2	Does your research involve pregnant women, human fetuses or neonates?		
3	Does your research involve cognitively impaired persons?		
4	Does your research involve traumatized and/or comatose patients?		
5	Does your research involve terminally ill patients?		
6	Does your research involve the elderly or those of advanced age that could have cognitive impairment or have been institutionalized?		
7	Does your research involve a higher rate of minority subjects than in the general population?		
8	Does your study involve deception of subjects?		
9	Does your research involve students and/or employees?		
10	Does your study involve survey or interview procedures with children as subjects?		
11	Is your research international?		
12	Does your study involve the observation of children in settings where investigator(s) will participate in the activities being observed?		
13	Does your research involve any undue influence or over influence either because of your relationship with the perspective subject or in the methods of communication employed to persuade them to participate ?		
For research using survey procedures, interview procedures, or observational procedures (Note: exemption is not allowed in surveys or interviews with children as subjects):			
14	If the data are to be recorded by audiotape or videotape, and the data were revealed, could this place the subjects at risk (psychological, social, physical, or legal)?		
15	Are subjects identifiable (e.g. by name or through demographic data)?		
16	Will data be collected and stored in a manner that participants may be individually identified?		
17	Will the collection of data include sensitive information (e.g. illegal activities, sexual orientation, sexual behavior, undesirable work behavior, or anything potentially embarrassing)?		

18	If subjects are identifiable either by name or through demographic data, are there potential risks to subjects if the data were revealed or disclosed?	☐	☐
For research using existing or archived data such as documents, records, or specimens: **"Existing means collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research.*			
19	Will any data, documents, records, or specimens be collected from subjects after permission is granted by the IRB to commence the research?	☐	☐
20	If the existing data are originally labeled with identifiers and are not publicly available, is the investigator recording the data in a manner that participants may be individually identified directly or indirectly through identifying links?	☐	☐
21	Is there any potential discomfort from questions, discussions, or interventions (mental or physical), anxiety, or tension in participants?	☐	☐

EXEMPT REVIEW CATEGORIES

Although the Federal government requires that copies of ALL research proposals involving human subjects be on file with the IRB, it does exempt certain types of research from full IRB review, see 45CFR 46.101(b).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- Research on regular and special educational instructional strategies, **or**
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless:

- Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject; **and**
- 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.

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 category 2 listed above, if:

- The human subjects are elected or appointed public officials or candidates for public office; **or**
- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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.

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:

- Public benefit or service programs;
- Procedures for obtaining benefit or service under those programs;
- Possible changes in or alternatives to those programs or procedures; **or**
- Possible changes in methods or levels of payment for benefit or service under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,

- If wholesome foods without additives are consumed **or**
- If a food is consumed that contains a food ingredient at or below the level and for a 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.

The below protion should be used to document the review, based on the information given, of this project by researcher in conjunction with the Human Protections officer (or their designee).

Tracking #_____ Reviewer's Name: _____

Data Initial Review Complete: _____

Exemption: ☐ Granted ☐ Not Granted

Exemption Category: ☐ Not subject to 45 CFR 46 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Conflict of Interest as a Reviewer

☐ I do not have a conflict of interest in reviewing this research application.

☐ I do have a conflict of interest and therefore I will report this to the IRB Chari so that another reviewer can be assigned to conduct the review

_____ _____

(Institutional Signature) **(Date)**