COLQUITT REGIONAL MEDICAL CENTER

IRB Determination Form

Colquitt Regional Medical Center's policy and federal regulations do not allow investigators to determine if their work or activity is human participants research and may require IRB review and approval. This form is designed to determine whether research is being conducted and if this research constitutes human participants research as defined by federal regulations (see 45 cfr 46.102). This form may be submitted to funding agencies when the agency requires documentation that the IRB has made the determination that IRB approval is not necessary to conduct the work.

I. Principal Investigator

Principal Investigator: (name of person submitting application)

Study Number:

Study Title:

Address:

Telephone:

Research ethics training source: ☐ NIH/NCI ☐ CITI ☐ Other:

Date Research Ethics Training Completed:

Funding source/agency (if applicable): ☐ Federal ☐ Other

Name of funding source:

If Request is being submitted by a student, please complete the following:

- Type of Student Research: ☐ Thesis ☐ Dissertation ☐ N/A
- Name of School/College:

- Department:
- Faculty Advisor Name:

Projected Data Collection Dates: From To

II. Proposal Summary

A. Provide a concise (3-5 sentences) summary of the purpose and rationale of the activity:

B. Describe the proposed methods and study procedures:

C. Describe how data collection will occur and the type of information to be collected about the subjects. Indicate whether data will be identified, de-identified, or coded. If coded, explain whether the code will be accessible to the investigators:

D. Do you intend to publish or present your results?

☐ Yes ☐ No ☐ Unsure

Note: The IRB does not necessarily define "human subjects research" based upon the intent to publish or present findings. Proceed to Section III.

III. Activities Determined by IRB Not to Represent Human Subjects Research

Indicate whether any of the below described activities associated with your project apply:

☐ Your project is limited to analysis of de-identified publicly available data. The IRB recognizes that the analysis of de-identified, publicly available data does not constitute human subjects research as defined in federal regulations, and that it does not require IRB review. Some examples of data available from large data consolidation bureaus and consortiums are Inter-University Consortium for Political and Social Research (ICPSR), U.S. Bureau of the Census, National Center for Health Statistics, National Center for Education Statistics, National Election Studies.

☐ Your project is limited to course-related activities designed specifically for educational or teaching purposes; where data is collected from and about human subjects as part of a class exercise or

assignment and is not intended for use outside of the classroom. Classroom research involving collection or utilization of data on human subjects will not require review from the IRB it if meets the following conditions:

1. The research results are not conducted with the purpose of creating generalizable knowledge.
2. The course instructor has completed human subjects research ethics training.
3. The research does not involve vulnerable populations (children, prisoners, pregnant women, or handicapped or mentally disabled persons).
4. The research poses minimal risk to the participants, meaning that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If any of the above is true, your activity is in a category that the IRB has determined not to represent human subject research and waived the requirement for submission to the IRB of an application for a human subjects research determination. However, it is recommended you document this determination by placing a copy of this completed application in your files to address any future queries about this project. This form may still be submitted for an official determination by the IRB if required by the sponsor.

IV. Federal Criteria for Research Involving Human Subjects

A. Does activity meet the federal definition of research?

Answer yes or no to the following:

The activity employs a systematic approach involving predetermined methods for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory.

☐ Yes ☐ No

The activity is intended to contribute to generalized knowledge by extending the results beyond a single individual or an internal unit (e.g., publications or presentations).

☐ Yes ☐ No

B. Does the activity involve human subjects according to the federal definition?

Answer yes or no to the following:

The investigator obtains specimens or data through intervention or interaction with a living individual (e.g., interviews, surveys, physical procedures, manipulations of the subject's environment, private or limited access internet sites, or any other direct contact or communication with a subject).

☐ Yes ☐ No

The investigator is obtaining identifiable private information about living individuals (e.g. chart reviews, lab studies on tissues or specimens, information from data or tissue repository).

☐ Yes ☐ No

The data or specimens are received by or provided to the investigator with identifiable private information.

☐ Yes ☐ No

The data or specimens are coded and the investigator has access to a link that would allow the data or samples to be identified.

☐ Yes ☐ No

Note: If you answered "yes" to both questions in Section IV.A **AND** "yes" to at least one question in Section IV.B **STOP**. Your activity meets the Department of Health and Human Services definition of human subjects research, and exempt, expedited, or full IRB review is required. For additional information regarding the review of human subjects research, please contact the IRB at 229-985-3003.

Otherwise, please proceed to Signatures V below.

V. Signatures

PRINCIPAL INVESTIGATOR: I will conduct the study identified above in the manner described on the attached narrative. If I decide to make any changes in the procedure, or if a participant is injured, or if any problems occur which involve risk or the possibility of risk to participants or others, I will immediately report such occurrences or contemplated changes to the Institutional Review Board.

P.I.'s Name: _____ Date: _____

Electronic Signature:

FACULTY ADVISOR (IF THE INVESTIGATOR IS A STUDENT, A FACULTY ADVISOR MUST SIGN BELOW): I have read and approved this protocol. I believe this is research as defined by the Department of Health and Human Services (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that the student is competent to conduct the activity as described herein.

Faculty Advisor's Name: _____ Date: _____

Electronic Signature: _____

Please save a copy of the form for your records and email the final form to Colquitt Regional's IRB Coordinator.

IRB Office Only

Date of Receipt: _____

Is the IRB Determination Form Complete? ☐ Yes ☐ No

Does activity meet the DHHS definition of human subjects research?

☐ Yes ☐ No