RESEARCH & SPONSORED PROGRAMS ADMINISTRATION
LAMAR UNIVERSITY™

Determination of Human Subjects Research

This form is to assist investigators in determining if research requires IRB oversight.
Please complete all sections then email to rspa@lamar.edu
The ORSPA will send you a Notice of Determination of Human Subjects Research, or will contact you with additional questions.

Investigator Name: **Department:**

Phone: **Email:**

Project Title:

Project supported by funding: ☐ **Yes** ☐ **No**

*Please name your funding:
(If pending, please state as such)

Purpose of the project: Provided a 3-5 sentence lay description, and what you hope to learn from this project.

Describe all project procedures: (if electronic survey, give name of survey)

QA/QI?

Quality Assessment and/or Quality Improvement: An activity conduced to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements.	**YES**	**NO**
Do you consider this project to meet the definition of QA/QI as noted above?	☐	☐
Will the activity involve randomization into different intervention groups?	☐	☐
Is the activity primarily designed to: • Improve a program or activity at Lamar University or to improve some other program? • Be applied to populations beyond your specific study population?	☐ ☐	☐ ☐

RESEARCH? [ORSPA & FDA]

Research: A systematic investigation designed to develop or contribute to generalizable knowledge.	**YES**	**NO**
Is the activity primarily designed to: • Improve a program at Lamar University, or improve some other program? • Be applied to populations beyond your specific study population?	☐ ☐	☐ ☐
Do you consider this project to meet the definition of **research**?	☐	☐
Is the activity a systematic investigation, including (but not limited to) a hypothesis, research development, testing, and evaluation?	☐	☐
Is the activity primarily designed to develop new knowledge?	☐	☐
Is the activity for a publication, scholarly presentation, thesis, or dissertation research?	☐	☐

ACTIVITY INVOLVES HUMAN SUBJECTS?

Does your project involve:	**YES**	**NO**
• Living individuals?	☐	☐
• Intervention, including manipulation of a person, or a person's environment?	☐	☐
• Interaction (through surveys, interviews, tests, or observations)? If "*yes*", attach the survey, interview, or test questions	☐	☐
• Obtaining identifiable private information **about** living individuals.	☐	☐
If this project uses existing data or specimens, answer the following:		
• Describe the source of the data. (i.e., from whom/where):		
• Is the data publicly available?	☐	☐
• Can the researcher identify the individual associated with the data?	☐	☐
• Is the data de-identified? If "*yes*", who did, or will, de-identify the data?	☐	☐
• Is the data coded? If yes, will you have access the key for the code?	☐	☐
• Was the data originally collected for this project?	☐	☐
• Was the data originally collected as part of clinical care?	☐	☐
• Was the data originally collected for research purpose under a Lamar University IRB approved protocol? If "*yes*" provide the IRB number: _____ If not obtained at Lamar, attached the consent form under which the data was obtained.	☐	☐

For ORSPA/IRB Use Only

Activity is <u>not</u> Human Subject research.

Activity is Human Subject research. IRB approval is required.

Signature_____ Date: _____