



Determination of Human Subjects Research
Application to the IRB

If there are **any questions** whether your project is **human subject research** you must submit this form to the IRB. Complete all sections then email to rspa@lamar.edu
The IRB will send you a **Notice of Determination of Human Subject Research**, or will contact you if needed.

Project Director:	Degree:	Title:
Dept/Div:	Phone:	
	Email:	
Project Title:		
Project supported by funding: No Yes *Please name your funding source in the text box Provided. If pending, please state as such. *If Federal funding, provide copy of grant proposal with this form.	This activity involves Conflict of Interest? No Yes – Contact the ORSPA at rspa@lamar.edu	
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 conducted 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: <ul style="list-style-type: none"> • Improve a program or activity at Lamar University or to improve some other program? • Be applied to populations beyond your specific study population? 		

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RESEARCH? [ORSPA & FDA]	
Research: A systematic investigation designed to develop or contribute to generalizable knowledge.	YES NO
Is the activity primarily designed to: <ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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:	
<ul style="list-style-type: none"> • 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 not Human Subject research.

Activity is Human Subject research. IRB approval is required.

Signature _____ Date: _____