The University of Texas Rio Grande Valley

Request for Determination That a Proposed Activity is Not Research Requiring IRB Oversight

1. Date:	

2. Title:	

3. Name and Address of Project Lead (PL):	
PL Name *(Last Name, First Name, MI):*	
Primary Affiliation:	
College/Department:	
Site, Building & Room #:	
PL's Telephone #	
PL's e-mail address:	
PL's Position Title:	
Other Project Team Members:	

4. Project Sites - List all sites where your project will occur	
Check all that apply	**Name of Institution / Site** *(list all participating sites below)*
	UTRGV / Department or Clinic:
	Knapp Medical Center Weslaco
	Valley Baptist Medical Center Harlingen
	McAllen Medical Center
	Other Department or Clinic Name:

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5: Is this regulated human research requiring IRB approval?
If you answer **Yes** to any question below, then IRB review and approval is required. If you are uncertain, then please call the Office of Research Compliance for further guidance to (956) 665-2093.

	Yes	No
1. The investigator will obtain data through **intervention**[1] or **interaction**[2] with **<u>living individuals</u>** • ***[1]Intervention*** *includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.* • ***[2]Interaction*** *includes communication or interpersonal contact between investigator and subject.*	☐	☐
2. The information obtained by the investigator is ***both*** **private[3] and identifiable[4]**. • [3]The information is **private** because it includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). • [4]The information is **individually identifiable** because the identity of the participant is or may be ascertained by the investigator or associated with the information	☐	☐
3. Is the intent of the project either to test a novel hypothesis or to replicate another researcher's original study?	☐	☐
4. Will patients or personnel be exposed to additional discernable risks or burdens beyond those of usual care at this institution?	☐	☐
5. Does the project involve withholding of any aspect of conventional care shown to be beneficial in prior well-conducted clinical trials?	☐	☐
6. Does the project seek to test interventions, practices or treatments that are not standard of care (neither consensus-based nor evidence-based)?	☐	☐
7. Will UTRGV or an affiliated institution receive a direct federal (DHHS) award to conduct human subjects research, even where all activities involving human subjects are carried out by a non-UTRGV entity (e.g., subcontractor or collaborator)? *Research Funding from the Department of Health and Human Services (DHHS) (e.g., Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); National Institutes of Health (NIH); etc.)*	☐	☐
8. Does the project involve a drug or device used outside of usual medical practice, including non-FDA-approved agents, or off-label uses of FDA-approved drugs or devices?	☐	☐
9. Will the safety and/ or effectiveness of a drug (FDA approved or non-FDA approved) or	☐	☐

regulated device be evaluated or be compared to that of another?		
10. Will data from the activity of an active group or a control group be submitted to, or held for inspection by the FDA in support of a marketing or research application for an FDA-regulated product (drug or device)?	☐	☐
11. Will the project be described as **research** in grants, public presentations, academic dossier or other representations? Note: QI findings may be published but should not be represented as research. UTRGV IRB can provide, upon request, documentation to journals that the project was determined to be non-research.	☐	☐
12. Does the project have funding from an organization with a commercial interest in the use of the results?	☐	☐
13. Will data obtained from use of a device on tissue specimens be submitted to, or held for inspection by, the FDA in support of a marketing application or research application for an FDA regulated product?	☐	☐

6. Classify your activity (Check the best choice)	
	Activities Not Considered Research
☐	**Health Surveillance**. Health surveillance is an ongoing part of the medical care and public health care functions closely integrated with timely **dissemination of these data to those responsible for preventing and controlling disease or injury** (may include emergent or urgently identified or suspected imminent health threats to the population to document the existence and magnitude).
☐	Routine **Quality Improvement** (QI) means systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. QI involves deliberate actions to improve care, guided by data reflecting the effects (e.g., types of practical problem solving; an evidence-based management style; the application of science of how to bring about system change; review of aggregate data at the patient/provider/unit/ organizational level to identify a clinical or management change that can be expected to improve care). For QI – answers to the following responses should be **YES**: 1. Are patients who receive the project intervention expected to benefit? 2. Will all groups in the project receive, at the minimum, usual care at this institution? 3. Is the purpose to measure the performance of or to determine the effect of a process change intended to improve health care delivery? 4. Will the results be used to inform and implement improvements in patient care at the institution the process is being implemented?
☐	**Medical Quality Assurance**. This refers to activities particular to an institution's QA program, such as those activities protected from disclosure by the Department of Veterans Affairs as part of its confidential medical quality-assurance program or other equivalent programs. (e.g., see VHA Directives or equivalent university or institutional policy)
☐	**Program Evaluation**. This refers to assessments of the success of established programs in achieving objectives when the assessments are for the use of program managers, for example, a survey to determine if program beneficiaries are aware of the availability of program services or benefits. [Note: Non-research evaluation is generally designed to assess or improve the program or service rather than to generate knowledge about a disease or condition.
☐	**Customer Satisfaction Surveys**. This refers to surveys of program users to obtain feedback for use by program managers. This is similar to program evaluation.

☐	**Class Projects**: academic projects or student assignments involving collection of data from human subjects when the data is used solely for the purpose of teaching course content and not intended to be used to develop or contribute to generalizable knowledge using the information collected as part of the class project. *Results will not be disseminated outside of the classroom setting.* **Requirements** 1. No studies that involve interaction with vulnerable subjects (e.g., pregnant women, children, prisoners, or individuals with impaired decision-making). 2. No identifiable data may be collected. 3. Data cannot be saved or shared outside the classroom. 4. Any recruitment must state that this is for a class project and will not be shared outside of the classroom. 5. May not include sensitive information. 6. It is recommended that students complete CITI training.
☐	**Case Reports**: use medical information collected from a clinical activity rather than a research activity and presented on no more than three (3) patients. Case reports are generally done by retrospective review of the medical record and highlights a unique treatment, case or outcome. The examination of the case is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that the HIPAA privacy rules are followed with respect to using or accessing PHI (a HIPAA authorization or waiver may be required)
☐	**Community Outreach**: The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of non-research community outreach activity is to prevent or control disease or injury and improve health, or to improve an ongoing community outreach program or service. Knowledge may be gained in any community outreach endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit patients participating in an outreach health program or a population by controlling a health problem in the population from which the information is gathered.
	Other: Describe here →

7. Summary of the Activity:
Provide a summary of the proposed activity. Provide sufficient detail for the reviewer to verify whether or not the activity is research and if research, whether or not it is "human research" requiring IRB approval as you have indicated above. If a separate activity description/written plan is available, attach it to this document.