UT Health San Antonio | Enterprise Research Management System (ERMS)

Request for Determination That a Proposed Activity is Non-Regulated or Not Human Research

Part A: Is the project ***regulated*** research?

	Yes	No
1. Will the project involve testing an experimental drug, device (including medical software or mobile app), or biologic? **If <u>any</u> of the following are true, the answer is Yes.** • Does the project involve use of a drug/device/biologic in one or more persons *outside of medical practice*? This means the drug/device/biologic is specified by the research and/or is not being provided by a practitioner to treat an individual patient based on the patient's own best interest. • Does the project evaluate the safety and/or effectiveness of a drug/device/biologic – either FDA-approved or non-approved? Does the project compare one or more drugs/devices/biologics? • Will data from the project be submitted to, or held for inspection by, the FDA, such as for purposes of research or marketing? This item applies even if the project does not involve living individuals or identifiable biospecimens.	☐ STOP! IRB review is required.	☒ Proceed to Q.2
2. Has the project received funding (e.g., federal, industry) to be conducted as a human subjects research study? **Has UT Health SA (or affiliate) received a <u>direct</u> award – grant, contract, or cooperative agreement – from any of these?** • NIH – National Institutes of Health • DHHS – Department of Health and Human Services • AHRQ – Agency for Healthcare Research and Quality • CDC – Centers for Disease Control and Prevention • Any industry sponsor or other federal agency	☒ STOP! IRB review is required.	☐ Proceed to Q.3
3. Is this a multi-site project (e.g., there is a coordinating or lead center, more than one site, and/or a study-wide protocol)? **If multiple sites are involved, the findings may be considered "generalizable." Contact the IRB Office for further guidance.**	☒ STOP! IRB review may be required.	☐ Proceed to Q.4
4. Is this a ***research*** project, i.e., a *systematic* investigation designed to contibute to *generalizable* (widely applicable) knowledge? **If the project involves any of the following, it may be regulated research:** • Testing a hypothesis • Randomization of subjects • Comparison of experimental vs. control • Observational research • Comparative effectiveness research	☒ Proceed to **Part C**	☐ Proceed to Q.5
5. Will the results of the project be published, presented, or disseminated outside of the institution conducting it? **Program evaluations and quality improvement projects can be published or presented, but they should not be described as research studies.**	☐ Proceed to Q.6	☐ Proceed to **Part B**
6. Will the project occur regardless of whether individuals conducting it may benefit professionally from it? **If the project is required to fulfill an educational prerequisite or mandated by the institution or another agency, the answer should be Yes.**	☐ Proceed to Q.7	☐ Proceed to **Part C**
7. Is the project intended to improve or evaluate the practice or process within a <u>particular institution</u> or a <u>specific program</u>? **If the project is for a wider audience or application, it may be considered "generalizable." Contact the IRB Office for further guidance.**	☐ Proceed to **Part B**	☐ Proceed to **Part C**

Part B: What type of ***non-regulated*** research is it?

Select the applicable item(s) below, and then proceed to Part E.

☐	**Case Report** Medical information collected from a clinical activity rather than a research activity and presented on no more than three patients. Typical features of a case report: • Retrospective review of the medical record • Highlights a unique condition, treatment, or outcome • Not a systematic investigation; no data analysis or hypothesis testing **Note: HIPAA regulations still apply – a HIPAA authorization or waiver may be required**
☐	**Quality Improvement (QI)** Systematic, data-guided activities designed to bring about immediate, positive change in the delivery of healthcare in specific settings. **All of the following must be true:** • The purpose is to measure the performance of, or determine the effect of, a process change intended to improve healthcare delivery. • Patients who receive the intervention are expected to benefit. • All patients will receive, at a minimum, the usual care at that institution. • The results will be used to inform improvements in patient care at the institution where the process is being implemented. Example: A new surgical timeout procedure implemented across the hospital
☐	**Medical Quality Assurance (QA)** Systematic activities designed to ensure compliance with standards by assessing whether a product, service, or process meets specified requirements and identifying errors or failures. QA is different from QI in that it typically measures programs or processes already in place, rather than implementing new ones. Example: A metric reviewed monthly to measure timely delivery of care
☐	**Program Evaluation** Assessments used by managers to evaluate the success of established programs or services in achieving objectives. Example: A survey to determine if beneficiaries are aware of the availability of particular benefits to which they are entitled
☐	**Customer Satisfaction Surveys** Surveys to obtain feedback from program or service users; similar to Program Evaluation. Example: A survey to solicit feedback on patients' satisfaction with their primary healthcare provider
☐	**Class Projects** Academic projects or student assignments involving collection of data from human subjects when the data are used solely for purposes of teaching course content and not intended to be used to develop or contribute to generalizable knowledge. Example: Collection of data on eye color or other genetic traits from family members to demonstrate concepts of heredity
☐	**Community Outreach** The primary intent is to prevent or control disease or injury and improve health, or to improve an ongoing community outreach program or service. Data may be generalizable, but primary intent is to benefit patients. Example: Educational session for new mothers on dental care for infants/toddlers
☐	**Health Surveillance** Medical and public health care functions closely integrated with timely dissemination of data to those responsible for preventing and controlling disease or injury. Includes activities authorized by a public health authority to assess onset of disease outbreaks or conditions of public importance. Example: A project to track local incidence of respiratory virus outbreaks across seasons
☐	**Scholarly & Journalistic Activities** Research where the focus is directly on the specific individuals about whom the information is collected, and used without extending that information to draw generalizations about other individuals or groups. Examples: Biography, oral history of a single subject, legal research, etc.
☐	**Criminal Justice & Intelligence Activities** Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or investigative purposes. Examples: Activities in support of homeland security, defense, intelligence, national security, etc.
☐	**Other:**

If the project fits within one of the above categories, IRB review is not required.

- Per federal regulations, the project is not regulated research as defined under 45 CFR 46.102.
- If the project results are disseminated, they should be characterized as quality assurance, program evaluation, etc.
- If any of the following are true, the project should be re-assessed using this form:
  - The project changes in a way that affects the intent or design.
  - The project parameters change to involve FDA-regulated products.
  - The project receives federal funding for human subjects research.

Part C: Does the research involve ***human subjects***?

	Yes	No
1. Will the *information* or *biospecimens* involved in the research be *from* or *about* **living** individuals? • This question applies regardless of identifiability or how samples are obtained. • If the information or biospecimens are from individuals now deceased, FDA and HIPAA regulations still apply.	☒ Proceed to Q.2	☐ Stop here.
If the answer to item 1 above is *No*, the research does not require IRB review.		
2. Will the investigator obtain, use, study, analyze, or generate the information or biospecimens through **intervention** or **interaction** with the individuals? **Intervention** includes: • Physical procedures or manipulations of the individuals, and/or • Manipulation of their environment for research purposes. **Interaction** includes: • Communication with the individuals, and/or • Interpersonal contact with the individuals.	☐ STOP! IRB review is required.	☒ Proceed to Q.3
3. Will the investigator obtain, use, study, analyze, or generate **identifiable private** information or **identifiable** biospecimens? **Private** information describes: • Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and/or • Information that has been provided for a specific purpose(s) in which an individual can reasonably expect that it will not be made public. **Individually identifiable** describes: • Information or biospecimens for which the identity of the participant is, or may be, ascertained, and/or • Information or biospecimens that may be associated with or linked to the individual by the investigator.	☒ STOP! IRB review is required.	☐ Proceed to Q.4
4. Will the investigator obtain newborn screening blood spots for research purposes (regardless of funding or identifiability)? Research using dried blood spots from newborn screening is considered human subjects research per federal law and requires IRB review and approval.	☐ STOP! IRB review is required.	☐ Proceed to **Part D**

If *any* of the above items is answered "Yes," the research involves human subjects.

- Federal regulations at 45 CFR 46 apply. IRB review is required. This form cannot be used.
- Refer to the color diagram at ERMS-IRB Help Center for which protocol and other study forms to submit.

If all of the above items are answered "No," please proceed with the following.

Part D: What is the ***non-human subjects*** research?

Answer the items below, and then proceed to Part E.

☐	Using anonymous pre-existing data or biospecimens.
	• Anonymous materials are those with <u>no</u> personally identifiable information contained in the original data or attached to the original specimen. • This includes *any* of the 18 HIPAA identifiers, such as dates of treatment or a code number. • If the date or specimen has a unique code traceable to a key with identifying information, this is not anonymous. Proceed to the next question.
☐	Using publicly available information that is not private.
	The information may or may not be identifiable.
☐	Using coded, pre-existing, or prospectively collected data or biospecimens.
	Select the applicable statement(s) below:

☐	The information/specimens were not – and will not be – collected specifically for the currently proposed research through an interaction or intervention with living individuals.
☐	The investigator never obtains identifiable information/specimens because (select the applicable statement(s) below):

☐	The key holder destroys the key before the data are provided to the investigator.
☐	The investigator and the key holder enter into an agreement prohibiting the release of the key under any circumstances or until the human subjects are deceased. ***Provide a copy of the HIPAA De-Identification Agreement.***
☐	There are laws or IRB-approved written policies for a repository or data management center that prohibit the release of the key to the investigator. ***Provide the study number of the applicable repository:***

Part E: Does the research involve an affiliate institution?

	Yes	**No**
1. Is South Texas Veterans Health Care System (STVHCS) a site, or will any VA patient data or biospecimens be utilized?	☐ Answer the items below	☐ Proceed to Q.2
Is there any non-federal funding associated with the project?	☐	☐
Will any data be transferred outside STVHCS? • Any transfer of data – including de-identified data – to any entity outside STVHCS requires information security and privacy reviews. • A data use agreement may be required. • **Contact the IRB Office for further guidance.**	☐ Proceed to Q.2	☐ Proceed to Q.2
2. Is University Health a site, or will any University Health patient data or biospecimens be utilized?	☐ Answer the item below	☐ Proceed to Part F
Will any data be transferred outside University Health? • Any transfer of data to any entity outside University Health – *including to UT Health SA* – requires review by the University Health Research Office. • **Contact the IRB Office for further guidance.**	☐ Proceed to Part F	☐ Proceed to Part F

Part F: Provide a brief summary of the research.

Summarize the project in sufficient detail for the reviewer to verify whether the activity requires IRB approval.

- Explain the purpose, background, rationale, outcomes to be measured, etc.
- Detail the source of data/specimens, coding plan for data/specimens, who holds the key, etc.
- Describe knowledge to be gained, as well as the intended audience or plan for dissemination.

If a separate research description or written plan is available, you may upload it within ERMS-IRB as part of your submission in lieu of adding a summary below.

☐ **N/A – See research protocol (or case report)**

Summary:

-Project will be ran at UTSA, as part of a dissertation. UTHSCSA will help supply the cortisol testing.
-Participants (N=15) will be analyzed at 3 time points, with 5 cortisol samples taken each day.
-The cortisol will be de-identified before being sent to UTHSCSA for processing.