|  |  |  |
| --- | --- | --- |
| 1. **UT Health San Antonio Tracking Number:** |  |  |

**Protocol Exception Definition:** The UT Health San Antonio IRB defines a protocol exception as a one-time, intentional action that departs from the IRB approved protocol for a single subject identified before it occurs and is under the control of the investigator (i.e., enrollment of a single subject who does not meet all eligibility criteria for a study, but the investigator and sponsor have agreed this subject should be enrolled).

**DO NOT USE THIS FORM FOR REPORTING protocol** [**deviations**](https://www.uthscsa.edu/vpr/services/glossary#Deviation/IRB) **and** [**violations**](https://www.uthscsa.edu/vpr/services/glossary#Violation)**. Refer to the** [**Deviation and Violation policy**](https://www.uthscsa.edu/sites/default/files/Services/forms/deviations_policy.pdf) **for tracking and reporting requirements.**

**Principal Investigator Responsibility:** Principal investigators are responsible for ensuring that their research is conducted according to the IRB-approved protocol. Use this form to request approval from the IRB ***prior to implementation of the exception*.**

***NOTE:*** ***When immediate action must be taken to eliminate an apparent unexpected hazard to the research subject, the PI may act without prior IRB approval. However, the PI must notify the IRB following the incident’s occurrence. (Refer to the*** [**Deviation and Violation policy**](https://www.uthscsa.edu/sites/default/files/Services/forms/deviations_policy.pdf) ***for reporting of*** [***emergency violations***](https://www.uthscsa.edu/vpr/services/glossary#Emergency-Violation)***)***

|  |  |
| --- | --- |
| **1. PI Name (Last Name, First Name, MI):** |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. PI’s telephone: |  | | PI’s e-mail address: | |  | |
|  | | | | | | |
| 1. PI’s Point of contact name & e-mail: | |  | | Point of Contact Phone Number: | |  |

|  |  |
| --- | --- |
| 3. State the protocol exception being requested |  |
| 4. Provide a rationale for this request |  |
| 5. How does the protocol exception affect the safety of subject? |  |
| 6. How does the protocol exception affect the integrity of the study? |  |
| 7. Does the protocol exception require a different informed consent **form or process** than the one currently approved by the IRB? | No  Yes |
| *If yes*, explain the consenting process you will use in relation to this protocol exception and attach any proposed informed consent documents that will be used. | Proposed informed consent attached |
| 8. Will data collected as a result of the exception be analyzed in a different manner from other collected data? | No  Yes |
| *If yes*, explain how it will be analyzed differently. |  |
| 9. Have you requested this exception for this protocol before? | No  Yes |
| *If yes*, explain why this will be another one-time exception, rather than a permanent change to the protocol. |  |
| 10. Identify any external organizations (i.e., sponsor or agencies) that have already approved of this request and provide documentation, if applicable.  ***NOTE: Documentation of approval by the sponsor is a requirement if this is an externally sponsored protocol*** | FDA  NIH  Sponsor  other  Approval documentation attached |
| 11. For subjects not meeting inclusion/exclusion criteria, has a colleague uninvolved (research team member) in the care of the subject provided an endorsement of the inclusion of the ineligible person because alternatives are limited to less favorable options?  ***NOTE: This is a requirement for all investigator-initiated protocols without a sponsor and investigator sponsored protocols*** | N/A – *not an investigator-initiated study*  No, *include reason for not obtaining endorsement:* |
| Yes – *complete name/department name of individual who provided an independent endorsement:* |

**Signature of PI**

Printed Name Signature Date