***North Texas Regional Institutional Review Board***

***University of North Texas Health Science Center***

***Application for Review: CASE STUDY Research (SINGLE SUBJECT Chart and/or Record Review)***

**Instructions: To assist with timely and appropriate reviews of case study research involving the analysis of a SINGLE subject’s clinical data (e.g., medical charts and/or records), please fill out this document. Note that this protocol must list a *full-time* (not adjunct or part-time) UNTHSC Faculty/Staff member or John Peter Smith (JPS) personnel as the Principal Investigator.**

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| **PROTOCOL INFORMATION** | **IRB Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **(Office Use Only)** |
| ***Title of Project*:**       |  |
| ***Name of Principal Investigator:***      ***Department:***       ***Phone:***       ***Email:***       |
| ***Name(s) of Key Personnel (co-investigator, student, resident, etc.)***:      ***Brief Description of this Case Study Research Project:***     ------------------------------------------------------------------------------------------------------------------------------------------------------**Note that ALL of the following items must apply to this Case Study for this project to be approved as EXEMPT category human subject research, as determined and to be confirmed by the Office of Research Compliance at UNTHSC:*** This Case Study research will involve a review of **existing medical and/or clinical care charts and/or records that have been generated as a matter of “standard of care”** (no experimental procedures or activities will be involved in this project).
* This Case Study research will involve records for **ONE patient** (who will become the subject in inquiry).
* Activity conducted for this Case Study research will respect the privacy of the subject and the confidentiality of information collected for research purposes. **NO identifiers of the patient-subject** will be recorded onto the research data set that will be developed, and all information collected for research purposes will be managed and held in strict confidence. All HIPAA regulations regarding the management of protected health information will be followed.
* All students, staff, and faculty associated with this Case Study research must have **completed adequate human subject research training** (such as CITI) *prior to the beginning of the project*. Documentation of adequate human subject research training must be submitted for each person listed as key personnel on this application.
* This Case Study research will involve **only UNTHSC and JPS affiliated** institutions, hospitals, clinics, sites, and practices where medical and/or clinical records will be maintained and assessed.
* This Case Study research will **only involve the analysis and reporting of existing information** (a so-called “retrospective study” in which the data to be analyzed are already available and in the medical chart and/or record). Note that the analysis of information not yet *in* the medical chart and/or record is considered a “prospective” review/study and is not allowed under this procedure. Contact the institution’s research office for procedures on obtaining IRB review and approval for prospective studies. For UNTHSC projects, contact the Office of Research Compliance at 817-735-0409. For JPS projects, contact the Office of Clinical Research at 817-702-3655 or ResearchSubmissions@jps.health.org.

I certify that the information provided in this request for CASE STUDY research (SINGLE SUBJECT Chart and/or Record Review) is complete and correct. I understand that I have the ultimate responsibility for protecting the confidential information of the subject and ensuring the privacy of the subject’s protected health information. I agree that the subject will not be identified by name in any presentation or publication related to this research project. Further, I attest that I, and any person listed as key personnel on this protocol, has legal and institutional authorization to access and examine the medical and/or clinical charts and/or records to be studied in this project, and I take full responsibility for their access and use of these records. **Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Signature of Co-Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Signature of Co-Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Attach Evidence of Human Subject Research Training** (e.g., a copy of a CITI completion certificate) for **each person listed** as key personnel. |