**Instructions for Completion of Form 1**

All clinical research activity involving the use of facilities, equipment, and/or personnel of Regional One Health must be reviewed and approved by the Chief Medical Officer prior to study initiation. Complete this application form and submit it to the Office of Medical Research, accompanied by all required documents. Incomplete submissions will not be considered. **Please allow 3- 4 weeks to process application**. For questions about research at Regional One Health, please contact the Office of Medical Research at 901-545-7453.

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| **Title of Project**: |
| **IRB#**:   | **IRB Approval Date**:**Clinical Trial #\*:**  |
|  (\* *if listed on ClinicalTrials.gov*)**Principal Investigator (P.I.)**: |
| **Position** *(please check)*: UT Faculty [ ]  Fellow [ ]  Resident [ ]  Student [ ]  Other: **Is PI credentialed at Regional One Health?** YES [ ]  NO [ ]  *(****Must review “Investigator Qualifications” on Page 2 before answering****)*:**Please note: If PI doesn’t meet the qualification criteria, he/she must include a Co-PI who does for research to be considered for conduct at ROH.** **List an IRB-approved Co-PI, if applicable:**   |
| **UTHSC College**: | **Department**:  |
| **PI A****ddress:**  | City:   | State: | Zip: |
| Phone: | Fax: | Email: |
| **Study Coordinator**:  | Phone:  | Fax: |
| Study Coordinator Email: |
| **Type of Study** (*Check all that apply)*:[ ]  Drug Study [ ]  Repository [ ]  Device Study – Device category: A [ ]  B [ ]  [ ]  Social / Behavioral Study[ ]  HDE / Humanitarian Use Device [ ]  Interview / Questionnaire[ ]  Prospective Observational study Please explain:  [ ]  Registry / Database Please explain:  [ ]  Chart Review – DATA SOURCE(S) (check all that apply): Medical Record (EMR/paper) [ ]  Laserfiche [ ]   Database/Registry [ ]  *\_ \_\_\_\_\_\_\_\_\_\_*\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(specify)*[ ]  Other Please explain:  |
| **Informed Consent / HIPAA Authorization**Project involves informed consent: YES [ ]  NO [ ]  If NO, IRB has approved waiver: YES [ ]  NO [ ] IRB has approved waiver of HIPAA authorization: YES [ ]  NO [ ] **Study Site(s)** *(please check all that apply)*: Regional Medical Center [ ]   Outpatient Center (880 Madison) [ ]  \_\_\_\_\_\_\_\_\_\_*\_\_\_\_*  Primary Care Network [ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* *(specify)  (specify)* Other:   |
| **Funding / Billing Information**:Project is investigator-initiated: YES [ ]  NO [ ] Project is funded:YES [ ]  NO [ ] ; If Yes, Funding Source/Sponsor: Will the Sponsor pay for all services and/or procedures provided under the study protocol (e.g., research purposes only, standard of care, data collection)? YES [ ]  NO [ ] .If NO, please identify specifically those research services and/or procedures that will not be paid for by the Sponsor:  |
| Support services will be required / purchased from Regional One Health: *(please check)* YES [ ]  NO [ ] If YES, *Request For Research Rates* form has been submitted: *(please check)* YES [ ]  NO [ ] If pharmacy services are required, investigational drug pharmacist has been contact for rates: *(please check)* YES [ ]  NO [ ] A contract [ ]  or purchase-order [ ]  will be issued.If services involve interpretation of tests by specialist physicians, e.g. EKG, X-Rays, etc., provisions are in place to prevent patient from being billed *(please check)* YES [ ]  NO [ ]  |
|  |

Anticipated Start Date:      End Date:       Study Duration:

**Signature of PI:**  **Date:**

**Signature of Co-PI:** **Date:**

**INVESTIGATOR CHECK LIST:**

***(Items to be submitted / addressed with the application)***

1. [ ]  Form 1 (Application for Approval to Conduct Research)
2. [ ]  IRB approval of HIPAA waiver has been obtained (if applicable).

 For chart review activities, investigators must obtain a HIPAA waiver from the IRB and submit such waiver letter as part of the application. HIPAA Authorization or Waiver must be obtained whenever patient charts are to be screened to identify patients who are eligible for inclusion in a study.

1. [ ]  Investigator Qualifications:

A Regional One Health-credentialed Principal Investigator must be identified for each research project. If the investigator is a student, resident, fellow, non-faculty member, or a faculty member whose expertise is not clinical, or if invasive methods (i.e., blood draws) are a part of the research protocol, a Co-Principal Investigator must be identified who is both a UT faculty member and a physician with privileges at Regional One Health and credentialed to practice in the specialty where the research is to be conducted. Faculty/student investigators will not need to seek credentialing from Regional One Health in order to conduct research at Regional One Health, provided a Co-Principal Investigator is so credentialed.

1. [ ]  A contract or purchase-order is needed if services are required from Regional One Health.

If applicable, a study-specific written contract for clinical research hospital services between the institution (e.g. UTHSC or UTMG) and Regional One Health is required. If no services are to be provided by Regional One Health, this should be stated in a cover letter (sample wording: “This will confirm our understanding that no services will be performed at Regional One Health which are chargeable to this Study; therefore, there will be no reimbursement to Regional One Health from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for services.”).

 *(Insert name of Institution)*

1. [ ]  There are research-related services for which Regional One Health will not be reimbursed.

Please provide an explanation in the cover letter.

1. [ ]  If conducting a chart review, please submit a copy of the data collection form.
2. **[ ]  Cover letter -** Include purpose, background/rationale, type of patient population, hospital unit/clinic involved (study site), indicate if ROH research services that are chargeable to the project will be required). The cover letter must clearly state the role of Regional One Health in the study and any special arrangements to be made. If necessary, the cover letter should also clarify any of the above items.

**Submit completed application form and required documentation to:**

***Office of Medical Research via*** ***awohabrebbi@regionalonehealth.org*** *or, via FAX at* ***901-515-9938***