Purpose: Completion of this form documents the requirements of the research duties UT Health Science Center San Antonio (HSC-SA) staff may carry out as they are assigned study protocols.

Responsibilities:
The employee and Principal Investigator (PI) complete the Research Scope of Practice (RScOP) form [Primary PI if more than one]. The PI verifies the employee’s competency to perform the research duty assigned. Submit the RScOP and Routing Form to the following institutional research office for approval:

a. HSC-SA licensed MDs, Professors, residents, and students engaged in human subject research (per their curriculum requirements) submit their forms directly to the affiliate per that institution’s policy.

b. All other HSC-SA employees submit their forms to the Office of Clinical Research (OCR).

c. Affiliate staff will submit forms as per their institutional policy.

Procedure:

1. Use current Research Scope of Practice for Research Personnel and Routing Form. The UT Health Science Center (HCS), the South Texas Veterans Health Care System (STVHCS), and at University Healthcare System (UHS) accept these forms.

2. Complete the form electronically using the item by item entry procedure in the next page.

3. Print the form. The PI initials the column labeled “Competency Verification” to indicate the verification of competency for each duty assigned and selected on the form (refer to: 8. Routine Duties on next page).

4. The employee reads and then signs the completed Scope of Practice Employee Statement Signature Page.
5. The PI signs the Principal Investigator Statement Page for the institution(s) applicable to the research. (e.g., sign both the HSC page and STVHCS page for HSC research being conducted at the STVHCS). Use addendum space for additional information or for the signatures of additional PIs.

6. Submit completed forms to OCR for institutional approvals to OCR for processing.

7. Always check the Office of Clinical Research (OCR) website to obtain the most current forms. Do not alter the format of the form (do not delete any of the set columns, rows, or change the content).

Item by Item Form Entries Procedure:

Routing Form

1. Enter Employee name, badge number, and position title.
2. Check applicable immigration status.
3. Enter employee’s primary department and division.
4. Enter employee’s email address.
5. Enter employee’s office telephone number or phone number where the employee can be reached.
6. Enter the Health Science Center School the employee is employed with.
7. Click on bullets by the name of institutional employer in the yellow section. Click on bullets of the locations where the employee will conduct research in the orange section. (Note: This section will also prompt the RScOP Coordinator to send an additional copy of the "Approved" RScOP to this institution).
8. Enter the Principal(s) Investigator(s) Name(s).
9. Use the field labeled “Send Additional Copy To:” for entering the name of an additional person who wants to receive a copy of the "Approved" RScOP form. This field is optional. If left blank, only the employee and PI will receive a copy of the “Approved” RScOP form.
10. Addresses for OCR and collaborating research offices are indicated at the bottom of the routing form.

Research Scope of Practice for Research Personnel Instructions:

1. NAME – Enter the name of the employee to whom the RScOP applies.

2. JOB TITLE – Enter the employee’s official job title.

3. DEGREE – Check all that apply for the employee.

4. LICENSURE/JOB TITLE – Check all that apply for the employee.
5. **PRINCIPAL INVESTIGATOR** – Enter the name of the PI for whom the employee will conduct research.

6. **DEPARTMENT/DIVISION** - Enter the department and the division under which your PI is employed.

7. **COMPLETION OF EDUCATIONAL REQUIREMENTS**
   a. Check if you completed the CITI Training and attach a copy of your “Completion Certificate” to your RScOP. If you need to complete the training, click here for instructions.
   b. Check if you completed the Clinical Research Training course and attach a copy of your “Completion Certificate” or check “PENDING”. All HSC employees must take an approved clinical research training course to meet the requirement of HOP 7.2.3 Research Scope of Practice for Study Personnel. If you need to enroll to attend the Clinical Research Training, click here to login to the Knowledge Center to retrieve this information or sign up for the next available Conducting Clinical Research training.
   c. Check if you completed the Human Research Protection Program (HRPP) module and attach a copy of your “Completion Certificate” to your RScOP. If you need to complete the module, click here to login to the Knowledge Center and complete the module.

8. **ROUTINE DUTIES** – Read the “Procedures” and “Note” Statements of page 1 of the RScOP form. Check all duties that apply to the employee. **Be sure to use the column appropriate to the employee’s professional licensure category If a block is shaded black within a column, the employee within that category cannot perform that duty** and it may not be part of their RScOP (e.g. Non-licensed staff may only be assigned duties that are not shaded black in the non-licensed category column). Some of the duties require the PI to verify competency in the “Competency Verification” column; the PI must initial in the column once he/she has verified the employee’s competency for the given duty. Duties which do not require competency verification for the particular professional category are shaded black on this one column.

   **Note:**
   a. Non-licensed personnel may not perform physical examinations. Non-licensed personnel performing any portion of physical assessments are required to additionally submit a signed Delineation of Physical Assessments for Non-Licensed Personnel form. Non-licensed personnel are only allowed to do the assessments as described in the form.
   b. If one of your assigned duties is stated as “ships biological materials”, you will need to submit a copy of your IATA Training Certificate with your RScOp form. If you need to take the Safety-Shipping Infectious
Substances, Clinical Specimens, and Dry Ice training, you can find it in the Knowledge Center > Course Catalog > Environmental Health and Safety.

9. ADDITIONAL DUTIES – Carefully consider the note on the form (Note: Clinical procedures that routinely require informed consent at the STVHCS, or at other HSC-SA affiliated institutions, even if performed for only research purpose, may only be performed by a Licensed Independent Practitioner). List any duties that are necessary to the research under the PI or within the department; include any appropriate license or proof of required training (for example, ‘Performs bone densitometry – Certified by “The International Society of Clinical Densitometry” from 8/10/2009 to 8/10/2011.’) Add an addendum page if necessary.

10. ELECTRONIC MEDICAL RECORD ACCESS NEEDED – Based upon the duties for this employee, determine the level of access he/she will need. Check the appropriate box, No access needed, Access needed, or Already has access. Enter the rational for access requested; (for example, “Needs to enter research notes into CPRS at the STVHCS,” or “needs to access data for research”.)

11. EMPLOYEE’S SIGNATURE – The PI should review the RScOP form with the employee prior to obtaining the employee’s signature. Before signing, carefully read the NOTICE TO LICENSED PROFESSIONALS and the RESEARCH EMPLOYEE’S STATEMENT. If you understand and agree with the statements, sign the form.

12. PRINCIPAL INVESTIGATOR’S SIGNATURE - The PI should review the RScOP form with the employee prior to obtaining the employee’s signature and signing the PI’s statement. The PI should carefully read the PRINCIPAL INVESTIGATOR’S STATEMENT (HSC-SA Investigator) before signing it. If you understand and agree with the statement, sign the form. An additional Supervisor, Department Chair, Service/Section Chief, PI or Co-PI for whom the employee works may approve the RScOP in the block provided, thereby also agreeing to the PI’s Statement. Use the addendum space for additional PI or Co-PI signatures and or comments. For multiple PIs, please refer to the Frequently Asked Questions on the OCR website click here.

13. ADDENDUM SPACES - Use the addendum spaces provided on the signature pages to add additional information and or you may attach an additional page as an addendum.

14. APPROVALS:
   Determine which Institutional Approvals are required.
   
   a. First, consider the research protocol:
      • If the research protocol is under the auspices of the South Texas Veteran Health Care System (STVHCS) obtain STVHCS approvals on page 5 of the form.
• If the research protocol is under the auspices of HSC-SA, obtain the HSC-SA approvals on page 6.
• If the research protocol is under the auspices of UHS, obtain the HSC-SA approvals first, then submit the RScOP form to UHS Research Office for completion of page 7 via the UHS process.

b. Second, consider who employs the employee to whom the RScOP applies:
• If the employer is HSC, obtain the HSC approvals on page 6 and submit completed forms to the Office of Clinical Research (OCR).
• If the employer is STVHCS, obtain STVHCS approvals on page 5 of the form.
• If the employer is UHS, obtain approval on page 7 of the form.

c. Examples:
• The research protocol is under the STVHCS and the employee works for HSC; both the STVHCS and HSC approvals are required (HSC employees submit to OCR).
• The research protocol is under HSC and the employee works for HSC; obtain only HSC Institutional approval (submit to OCR).
• The research protocol is under HSC and the employee works for HSC, research is at UHS, obtain both UHS and HSC institutional approvals (HSC employees submit to OCR).
• The research protocol is under HSC and the employee works for UHS, obtain HSC approval, submit RScOP to the UHS Research Office.
• STVHCS employees, engaged in STVHCS human subject research, submit the forms to the office of ACOS for Research & Development at STVHCS.
• UHS employees, engaged in UHS human subject research, submit the RScOP to the UHS Research Office.

15. Send completed forms to the Office of Clinical Research.