

Instructions for Completing the Research Scope of Practice Form
Revised August 7, 2008

INSTRUCTIONS FOR COMPLETING THE SCOPE OF PRACTICE FORM

Overview

1. The current [Research Scope of Practice](#) Form and [Routing](#) Form must be used.
2. The employee and Principal Investigator (PI) [Primary PI if more than one] complete the Research Scope of Practice form. The column labeled "Competency Verification" must be initialed by the PI to indicate the verification of competency for the duty listed (see subsequent directions).
3. The employee read and signs the Scope of Practice Employee Statement Signature Page.
4. The PI will sign the Principal Investigator Statement Page for the institution(s) applicable to the research. (e.g., UTHSCSA page and VA page are signed for UTHSCSA research being conducted at the VA). Addendum space may be used for additional information or for the signatures of additional PIs.
5. The forms are submitted to the applicable institutional research office for approval (See bottom of routing form).
6. The Research Scope of Practice Form can be completed electronically but must be submitted as a hard copy with original signatures for processing.
7. Always check the OCR website to obtain and to use 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).

Research Scope of Practice Form Directions

1. **NAME** – Enter the name of the employee to whom the Research Scope of Practice 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** – The name of the PI for whom the employee will conduct research
6. **DEPARTMENT/DIVISION** - Enter the department and the division under which you are employed and the division (e.g. Medicine/Cardiology).
7. **COMPLETION OF EDUCATIONAL REQUIREMENTS** – All UTHSCSA employees performing research with human subjects are required to complete the CITI training. An employee can obtain the date he/she completed training by printing their certificate from the CITI web-site. (The IRB also has privileges to confirm an employee's completion of CITI training.)

If the employee completed the Office of Clinical Research (OCR) training course, enter the date completed. The employee can confirm the date by accessing their course information on Knowledge Center or contacting the Office of Clinical Research. If an alternate course, such as SOCRA, ACRP, or FDA sponsored GCP is being used, first confirm with the OCR that it is acceptable, and enter the course name, the sponsor of the course, and the completion date on the form. Attach a copy of the certificate of attendance if you attended a course other than the OCR training course.

8. **ROUTINE DUTIES** – Read the "**Procedures**" and "**Note**" Statements of page 1 of the Research Scope of Practice form. Check all duties that apply to the employee. **Be sure to use the column appropriate to the employee's licensure category** (refer to note). **If a block is shaded black within a column, the employee within that licensure category cannot perform**

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that duty and it may not be part of their Research Scope of Practice (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 are shaded black on this one column.

9. **ADDITIONAL DUTIES** – Carefully consider the note on the form (*Note: Clinical procedures that routinely require informed consent at the STVHCS, or at other UTHSCSA 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 8/10/2003 to 8/10/2008.’) 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 have access*. Enter the rationale for access requested; for example, “Needs to enter research notes into CPRS at the VA,” or “needs to access data for research.”
11. **EMPLOYEE’S SIGNATURE** – The PI should review the Research Scope of Practice 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 Research Scope of Practice 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 (UTHSCSA 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 should also approve the Research Scope of Practice in the block provided, thereby also agreeing to the PI’s Statement. The addendum space may be utilized for additional PI or Co-PI signatures and or comments. For multiple PIs please refer to the Anticipated Questions <http://research.uthscsa.edu/ocr/> on the OCR website.
13. **ADDENDUM SPACES** - You may use the addendum spaces provided on the signature pages to add additional information and or attach an additional page as an addendum.

APPROVALS

1) Determine which Institutional Approvals are required.

- a. First, consider the research protocol.
 - o If the research protocol is under the auspices of the VA, obtain VA approvals on page 5 of the form.
 - o If the research protocol is under the auspices of UTHSCSA, obtain the UTHSCSA approvals on page 6.
 - o If the research protocol is under the auspices of UHS, obtain the UTHSCSA approvals first, then submit the scope form to UHS Research Office for completion of page 7 via the UHS process.

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- b. Second, consider who employs the employee to whom the Scope applies.
If the employer is the VA, obtain VA approvals on page 5 of the form.
If the employer is UHS obtain approval on page 7 of the form.
If the employer is UTHSCSA, obtain the UTHSCSA approvals, page 6.

Examples:

The research protocol is under the VA and the employee works for UTHSCSA; both the VA and UTHSCSA approvals are required.

The research protocol is under UTHSCSA and the employee works for UTHSCSA; only UTHSCSA Institutional approval is required.

The research protocol is under UTHSCSA and the employee works for UTHSCSA, research is at UHS, both UHS and UTHSCSA institutional approvals are required.

The research protocol is under UTHSCSA and the employee works for UHS, UTHSCSA approval is required, Scope of Practice for Research Personnel is submitted at the UHS Research Office.

If the Research Scope of Practice requires Institutional Approval for *the VA only*, submit to the office of ACOS for Research & Development.

UHS employees engaged in research submit the Scope of Practice for Research Personnel to the UHS Research Office.

INSTRUCTIONS FOR COMPLETING THE ROUTING FORM

EMPLOYEE INFORMATION:

1. Enter the information for the employee to whom the Scope applies
2. Enter the full first and last name; include the degree/title if applicable (e.g. MD, PhD, DDS)
3. Enter official position title
4. Enter the UTHSCSA, UHS or VA employee ID number, as applicable
5. Select the appropriate box to designate his/her employer, i.e. UTHSCSA, UHS or VA
6. Select the location where the employee conducts/administers research activity
7. Enter the Department/Division in which the employee works (e.g. Medicine-Cardiology)
8. Enter the School (e.g. Dental School; for UHS and VA, this is not applicable)
9. Enter the institutional e-mail address and phone number

PRINCIPAL INVESTIGATOR INFORMATION:

1. Enter the **PI(s)** information for whom the employee is working for, conducting research with, or whose signature is on the Research Scope of Practice form
2. Enter PI full name, degree, email, phone and employer

Attach the Completed Routing Form to your completed Research of Scope of Practice Form and submit to your institution to obtain the appropriate signatures and for processing.