

Frequently Asked Questions
Re: OCR Research Scope of Practice Policy & Form
Revised July 28, 2008

1. **To which UTHSCSA Schools does this policy release apply, and who are the approving deans?**

School of Medicine – Robin Brey, MD, Associate Dean for Research
School of Nursing – Carrie Jo Braden, PhD, RN, Associate Dean for Research
School of Allied Health Science – Marilyn Harrington, PhD, Dean

2. **Do I need to submit a separate Research Scope of Practice form for each investigator I work with, or for each different protocol that I work with?**

No. The Research Scope of Practice is not protocol specific. The form is intended to state the duties that you are allowed to perform in your role/practice. The PI signature page (page 5) of the form has an additional line that may be signed by your Supervisor, Department Chair, or Service Chief. Addendum space is provided or you may add an addendum page for additional investigator signatures. **If your duties are modified**, the policy does require that you submit an updated Research Scope of Practice form.

3. **Does the modified Research Scope of Practice replace the previous Research Scope of Practice?** Yes.

4. **Does the 2-year cycle restart with the modification?** Yes.

5. **As the modified form is routed for approval, should a copy of the previously submitted form be attached for reference?** Yes.

6. **I just saw the new version of the Research Scope of Practice form (May 2008). I just submitted one two months ago, does this mean I need to submit a new one again?**

No. If you have a current Research Scope of Practice that was submitted using the previous form, you do not need to resubmit with the current form until your two year cycle for renewal is reached. (e.g. If you submitted one in August 2007 you will not be due to submit another one until August 2009 unless your duties are modified).

7. **How is the IRB going to require that the Principal Investigator (PI) verify the Scope of Practice?**

The IRB added this requirement in Form B-2 Study Personnel and in the “Roles and Responsibilities of the Study Staff” section of the Progress Report for Continuing Review form.

8. **Will the UTHSCSA Institutional Approvals be sequential or parallel?**

The approvals will be parallel, which serves to reduce the time for approval.

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9. Which PI signs and verifies if I work with more than one PI?

Have your primary investigator or your departmental supervisor sign. Keep in mind that the Research Scope of Practice is not protocol specific and is submitted every two years unless duties are added or modified.

10. How do I determine what institutional approvals are required (i.e. UHS, VA and/or UTHSCSA)?

First--consider who employs the employee to whom the Scope of Practice applies:

- If the employer is the VA, obtain VA approvals on page 5 of the form.
- If the employer is UTHSCSA, obtain the UTHSCSA approvals, on page 4.
- If the employer is UHS, obtain the UHS dates of approval, and signature page 6.

Second--consider where you will be conducting research:

- If the research protocol is under the auspices of the VA, obtain VA approvals on page 5 of the form.
- If the research protocol is under the auspices of UTHSCSA, obtain the UTHSCSA approvals on page 4.
- If the research protocol is under the auspices of UHS, obtain the UTHSCSA approvals first, then obtain the UHS approvals on page 6 via the Research Office.

Examples:

- The research protocol is under the VA and the employee works for UTHSCSA; both the VA and UTHSCSA Institutional 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.

11. Do PIs need to complete the Research Scope of Practice Form for themselves?

Not at the HSC if they are members of the faculty or a licensed provider. The policy applies to the following personnel engaged in research:

- Research fellows (non-ACGME) working as research coordinators, project coordinators, or research assistants
- Research coordinators, project coordinators, and other unlicensed personnel
- Research nurses, nurse practitioners, physician assistants, psychologists, podiatrists, optometrists, etc.

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12. What are the basic steps to follow?

- a. Read the instructions for completing
- b. Fill in cover front sheet and the Research Scope of Practice Forms
- c. Make sure that all verified competencies are initialed by the PI on the last column and that all applicable signatures are obtained and dated
- d. If you are working with the transportation of biological specimens don't forget to submit a copy of your IATA training certificate. Training can be obtained for free at:
<http://research.uthscsa.edu/safety/transport.shtml>
- e. If you cannot remember the date you took courses, check your personal profiles at the UT Health Science Center Knowledge Center for dates of the Conducting Clinical Research Course and the CITI website for the required CITI ethics course
- f. Finally take the packet to:
 - The Office of Clinical Research (UTHSCSA employees)
 - The Office of Research and Development at STVHCS (VA employees)
 - UHS Research Department (UHS)
 - If none of above apply, take to the office of the institution where the research will be conducted

13. Where may I obtain more information? For information about the policy, the form, or the administration of the Research Scope of Practice process contact:

Office of Clinical Research (OCR)
210-567-0651
Room 431A
OCRmail@uthscsa.edu