

New Name and structure for Institutional Review Board

The UNTHSC Institutional Review Board (IRB) has changed its name to reflect a new partnership and collaboration with the John Peter Smith (JPS) Health Network. The new name is “The North Texas Regional IRB “. The North Texas Regional IRB is a collaboration involving UNTHSC and the John Peter Smith (JPS) Health Network to provide human subject protection review services to both UNTHSC and JPS researchers...in a single IRB framework. As a Regional IRB, other collaborations are possible throughout the North Texas region, hence the name “North Texas Regional IRB”. As new collaborating partners become involved with the North Texas Regional IRB, announcements will be sent out regarding these new partnerships and opportunities.

Practical implications for UNTHSC researchers:

- The IRB website and all IRB forms and applications have been modified to reflect this name change.
- In addition, some IRB forms have new elements to reflect the partnership with JPS. We recommend using the new forms for all IRB applications and processes (new, continuing review, final reports, etc.).
- Materials using old versions of the forms and templates that have already been submitted will still be reviewed (no need to re-submit these documents)...but we encourage the use of the new forms as soon as possible. The “old” IRB application forms and templates will not be accepted after March 1, 2018.

FAQs about the North Texas Regional IRB

What is the North Texas Regional IRB?

The North Texas Regional IRB is a collaboration involving UNTHSC and the John Peter Smith (JPS) Health Network to provide human subject protection review services to both UNTHSC and JPS researchers...in a single IRB framework. As a Regional IRB, other collaborations are possible throughout the North Texas region, hence the name “North Texas Regional IRB”.

Why is there a North Texas Regional IRB (why not continue with the IRBs as before)?

Investigators desiring to conduct human subject research at more than one institution often need to obtain IRB approval from each institution where they plan to be engaged in research. Generally, this requires review by two or more different IRB’s, each with its own forms, processes, procedures, timelines and review schedules. Invariably, this can create delays as well as some “back-and-forth” modifications as each IRB may require different elements in consent forms and other documents. To minimize delay and streamline the review and collaborative research process involving the two organizations, both UNTHSC and JPS have agreed to combine resources and policies into a single Regional IRB. It is expected that other institutions will join in this effort, bringing even more collaborative opportunities and efficiencies to human subject research and protection.

How is this different from the previous UNTHSC IRB?

For UNTHSC researchers, this is essentially a name change. The same Office of Research Compliance will be the entry point for human subject research protocol submissions as usual.

However, what IS different is that, for those investigators planning to conduct research at JPS, instead of needing IRB approval from both institutions, only one IRB review and approval will be required...from the North Texas Regional IRB.

You may notice that the content of IRB forms and templates is a bit different from prior versions, so be sure to use the CURRENT (as posted on the IRB website) versions of these forms.

What if I submit a NEW application using “old” forms or templates?

During this transition process, the “old” forms and templates will be accepted for a short time period to allow investigators to become aware of and familiar with the new forms. Researchers are encouraged to use only the current web-posted North Texas Regional IRB forms and templates for their IRB-related document submissions. After **March 1, 2018**, if an investigator submits an older (UNTHSC IRB or JPS IRB) form with any new submission or continuing review/final report, it may be sent back to the investigator unreviewed for re-submission using the new forms/templates.

Where do I submit my IRB Application / Packet?

For **UNTHSC** researchers, the *Office of Research Compliance (ORC)* continues to be the same entry point for human subject research protocol submissions. No changes there! We are still located in CBH Suite 160 and our contact information remains the same.

For **JPS** researchers, please send all materials to the *Office of Clinical Research (OCR)* located at John Peter Smith (JPS) Health Network (see contact information below) for initial intake and processing. All communications from North Texas Regional IRB will be sent to JPS researchers through the Office of Clinical Research.

JPS Health Network
Office of Clinical Research
1500 S. Main Street
Fort Worth, TX 76104

Office Number: 817-702-3655
Email: ResearchSubmissions@jpshealth.org

I already have IRB approval for my project(s) from the UNTHSC IRB...do I have to re-submit anything?

No. If your research project has already received UNTHSC IRB approval nothing will change until your next continuing review or modification request. At that point, you will need to update any consent form(s) to state the new name for the IRB: “North Texas Regional IRB”. All IRB contact information (phone numbers, etc.) remains the same.

Will my current CITI training be accepted for this “new” IRB?

Yes. For UNTHSC as well as JPS personnel, all current IRB-approved CITI training certificates are still valid.

What about the IRB Conflict of Interest (COI) Form?

Conflict of Interest (COI) disclosures associated with a specific human subject protocol (so-called IRB-COI Forms) are the same, except for the name change.

Will there be any change from my previous IRB staff interactions and this “new” IRB?

There shouldn't be, since all the same folks are still here! The UNTHSC Office of Research Compliance will be adding new staff to address the increasing workload. So, during this transition period as we absorb protocols from JPS in addition to expanding research at UNTHSC, we ask for your patience regarding any delays you might experience.

What about Clinical Trials? How do I submit those to the IRB for review?

As before, if your industry-sponsored project has a UNTHSC faculty member as principal investigator, the project must be submitted through the UNTHSC Office of Clinical Trials.

When the principal investigator is an employee of JPS or Acclaim Physicians Group, the protocol documents must be submitted through the JPS Office of Clinical Research (not the UNTHSC Office of Clinical Trials). For more guidance on that step, see ***SPECIAL INFORMATION FOR JPS Health Network / Acclaim personnel.***

SPECIAL INFORMATION FOR JPS Health Network personnel:

The JPS Institutional Review Board has now merged with the UNTHSC IRB to form the multi-institutional ***North Texas Regional IRB***.

Personnel employed by JPS Health Network planning to conduct human subject research must download and complete the relevant IRB forms from the North Texas Regional IRB website provided below:

<https://www.unthsc.edu/research/protection-of-human-subjects/institutional-review-board-forms/>

Please note, the current JPS IRB forms will expire March 1, 2018.

The site above also provides a wealth of guidance and information about human subject protection and relevant federal and institutional guidelines, regulations, policies and procedures.

JPS researchers must submit their completed IRB application materials to the JPS Office of Clinical Research (OCR). OCR will then review the application materials for content and completeness before forwarding it to North Texas Regional IRB for review. OCR serves as the mediator between North Texas Regional IRB and the investigators.

Please note that all JPS investigators must comply with all JPS research policies, procedures and submission requirements **before** the protocol application packet will be sent to the North Texas Regional IRB for review.

Protocols that are sent directly to the UNTHSC Office of Research Compliance for IRB review, rather than through the JPS' Office of Clinical Research (OCR), will be promptly returned to the investigator without IRB processing or review.

JPS investigators who have any questions about the IRB submission process, should contact the JPS Office of Clinical Research at (817) 702-4186 or ResearchSubmissions@jpshealth.org