

REVISED: September 24 - 2018

TO: Investigators, Research Coordinators, IRB Members, Research Community
FROM: The Office for the NORTH TEXAS REGIONAL IRB
SUBJECT: Update on IRBNet

Dear Colleagues,

As you now know, the North Texas Regional IRB has adopted IRBNet as our electronic software system for management, submission, review and oversight of human subject research protocols.

Some target dates and information to keep in mind:

Logging on / Creating an Account in IRBNet:

- Right now, you may access IRBNet from virtually any computer using a web browser by visiting www.irbnet.org. At this site, you may then self-register and create your own User ID and Password, as part of the JPS and UNTHSC research community, and immediately begin using these exciting new tools. **Please note that IRB review will not proceed until the Principal Investigator has been given FULL access to a protocol.**

Submitting NEW Protocols:

- Since **September 1, 2018**, all **NEW protocols** (Exempt, Expedited and Convened [Full Board] protocols) must be submitted electronically via IRBNet, and all review decision letters will be issued electronically via IRBNet.

Modifications and Amendments to existing studies (not yet in IRBNet):

- Modifications and Amendments: For existing projects...to assist in a smooth transition, **all Modifications (Amendments) will continue as PAPER-BASED submissions (NOT through IRBNet) until those projects come up for Continuing Review (Progress Reports)**. Please disregard previous communication or instruction that modifications and amendments need to be submitted through IRBNet on or after October 1.

Continuing Review (Progress Reports)

- **Starting October 1, at the time of Continuing Review (Progress Report), submit all documents through IRBNet.** (In other words, continuing review of your project triggers IRBNet submission and activity).

When submitting your continuing review package via IRBNet, it is critical that all of the current documents for your study are uploaded into IRBNet. Such documents include, but are not limited to: protocol synopsis, consent form(s), questionnaires, investigator brochures, sponsor protocols, DSMB reports, etc. This will help to ensure that all appropriate documents for the study are electronically accessible (to both the study team and the IRB) for the life of the study. Consult the many tools, pdf files and videos provided on the IRBNet site for how these processes work.

NOTE: If you will be submitting an amendment/modification with your continuing review, please contact the IRB Office for instructions on how to submit in IRBNet.

Close-Outs/ Final Reports

- If your study is not yet “in” IRBNet, then for Final reports, (“Close-outs*”), use paper submission process as usual. Thus, if you will be closing your existing study **prior** to transitioning it to IRBNet, please submit the appropriate closure form (“*Sponsored Clinical Trials – Final Report (Close-out Form)*” or “*Investigator-Initiated Projects – Final Report (Close-out Form)*”) to the North Texas Regional IRB *in paper*. Studies that will be closed **prior** to their next continuing review (and that will **not** be amended) will be closed out in paper, and will **not** need to be transitioned to IRBNet.

SAE (Serious Adverse Event) and UAP (UnAnticipated Problem) Reports for existing studies (not yet in IRBNet):

- SAE and UAP Reports: For existing projects...to assist in a smooth transition, all SAE and UAP reports will continue as PAPER-BASED submissions (NOT through IRBNet) *until those projects come up for Continuing Review (Progress Reports)*.

Reminders:

- **Do not** contact the IRBNet.org people directly for any issue or question about process, procedure, forms, or documentation...**contact our office instead.**
- All PIs, investigators, and pertinent research personnel will need to register for an IRBNet account in order to be granted access to a study. Without access, key personnel on a study will not be able to view or make any necessary revisions to the protocol, and will not receive correspondence from the IRB regarding a protocol. In addition, please be sure to grant pertinent research personnel the appropriate level of permission access (full, write, read and no access).

NOTE: Please note that if your studies involve CDC and commercial IRBs, guidance on how to enter the information into IRBNet is forthcoming. Please contact the IRB office on the process for submitting these during this transition.

As usual, for assistance and information please contact the following persons who can assist you with any questions you may have as we move forward with this important initiative.

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Once again, the North Texas Regional IRB is pleased to bring these robust new tools to our research community. And, please feel free to share this email with any of your colleagues who may not be (yet) on our email routing list.