UTHSA Research Protection Programs - Research Forum

Trial Innovation Network
Shweta Bansal, MD, FASN

Updates from the IRB Office
Wanda Quezada, CIP

February 23, 2023
During the Forum:

- **Webinar Housekeeping** – Mute your mics to avoid echoing or background noise. Avoid activating your camera to preserve bandwidth.

- **Q&A** – In lieu of voicing your questions, use the chat function, a moderator will respond to your question. We will leave 5 minutes after each presentation for questions.

- **Recording** - This session is being recorded and the full presentation and slides will be available on the VPR website. [https://www.uthscsa.edu/vpr/services/](https://www.uthscsa.edu/vpr/services/)
Engaging with the Trial Innovation Network

Shweta Bansal, MD
Director, TIN-Liaison Team
Institute for Integrating Medicine and Science
(Clinical Translational Science Award- CTSA)
University of Texas Health San Antonio
1. Trial Innovation Network (TIN) – What is it?

- TIN is a NCAT support system for better, faster and cost-effective multi-site investigator-initiated clinical trials.
- It is a collaborative partnership with Investigators at the 60+ hubs in the national CTSA network.
The trial Innovation Network

The vision of the TIN is to innovatively address critical roadblocks in multi-site clinical research and accelerate the translation of novel interventions into life-saving therapies.

Mission

• To leverage the talent, expertise, and resources of the CTSA program
• To act as a national laboratory to study, understand, and improve multi-site trials
• To inform healthcare by supporting successful multi-site trials that answer important clinical questions
Agenda

1. The Trial Innovation Network
2. Resources and Support
3. Resources in Action
4. Submission Process
5. The TIN at Work
6. Key Takeaways

October 2006
First group of funded CTSA hubs launched the consortium under the National Center for Research Resources

Date - UTHSA
3rd Cycle: 2018-2023
4th Cycle: Application submitted

Fall 2016 - Renewed
NCATS launches Trial Innovation Network (TIN) to help researchers carry out multicenter clinical trials better, faster, and more cost-efficiently
2. How Does TIN Support?

Proposal Process

The Trial Innovation Network offers investigators the opportunity to request consultations and resources for multicenter clinical trials and studies. These are designed to help investigators, for example, develop proposals into protocols, enhance study operations, or improve recruitment and retention. Some consultations developed into clinical protocols may be implemented in the Network and within the CTSA Program.
Process of TIN Support

The TIN offers investigators the opportunity to request consultations and resources for multi-center clinical trials and studies across disciplines and disease areas.

**Initial Consultation**
All proposals accepted into the TIN portal are provided with an initial consultation.

**Resources**
Requests for additional resources are put forward for internal approval.

**Comprehensive Consultation**
The investigator and TIN work together to develop and submit a proposal.

**Trial Implementation**
The TIN serves as the trial data or clinical coordinating center.
3. Two Ways to Get involved in the TIN

• Investigators can submit their own proposals for multi-site trials to the TIN; the next page outlines how to submit.

• The local TIN Liaison Team will connect investigators with multi-site clinical trials initiated by other network sites.
Three reasons why you should partner with the TIN

**Operational Innovation**
The TIN provides expert methodological and logistical guidance and draws on evidence-based strategies for success, which allows you to focus on the science.

**Excellence**
The TIN helps to improve the multi-center study process by leveraging the national CTSA network and taking advantage of established infrastructure.

**Collaboration**
The TIN connects you and your team with relevant experts, works in partnership with other NIH Institutes and Centers, and provides access to the entire CTSA network.

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**TRIAL INNOVATION NETWORK**
Operational innovation, excellence, and collaboration.
Local Liaison Team

• Liaison Teams are the front line of the Trial Innovation Network
• Each CTSA Program Hub has its own Network Liaison Team
• There are more than 300 Hub Liaison Team Members across the CTSA
• Liaison Teams:
  – Connect the CTSA hub to the TICs and the RIC
  – Encourage investigators to submit to the TIN
  – Facilitate implementation of TIN trials to Hubs

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Robert A. Clark, MD
clarkra@uthscsa.edu

CTSA Liaison Team Director
Shweta Bansal, MD
bansals3@uthscsa.edu

Point of Contact
Karen Nijland
NijlandK@uthscsa.edu
Initial Consultation

- Study Design
- Study Budget
- Projected Timelines
- Recruitment
- Study Feasibility (e.g. PAR & IC interest)
- Innovations in Clinical Effectiveness Trial Design
Resources

- Standard Agreements
- Single IRB Support*
- Recruitment and Retention Plan
- Recruitment Feasibility Assessment
- Recruitment Materials
- Community Engagement Studio
- EHR-Based Cohort Assessment
- Innovations in Clinical Effectiveness Trial Design

*Cost must be included in trial budget
Comprehensive Consultation

- Integrated partnership
- More consultation hours
- Study feasibility and recruitment plan
- Protocol development
- Site identification
- Budget refinement
Trial Implementation*

*All costs related to trial implementation must be included in trial budget
## Use Cases of TIN Consultations

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Therapeutic area</th>
<th>Trial characteristics</th>
<th>TIC and RIC support</th>
<th>Dates</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Consult</strong></td>
<td>Neurology</td>
<td>Phase 2B; unblinded, randomized prospective trial; 100 participants; 9 sites; 4 years; I/C: NINDS</td>
<td>Study planning support (design, budget, timelines, feasibility)</td>
<td>01/2018 – 06/2018</td>
<td>Paused 06/2018; PI didn’t have the bandwidth</td>
</tr>
<tr>
<td><strong>Provision of Resources</strong></td>
<td>Cardiovascular diseases</td>
<td>Multicenter observational study; 1,500 participants; 25 sites; 5 years; funded: Foundation Funding</td>
<td>EHR-based cohort assessment and CTSA site selection</td>
<td>12/2018 – 05/2019</td>
<td>Funded 05/2015, recruited additional CTSA</td>
</tr>
<tr>
<td><strong>Comprehensive Consult</strong></td>
<td>Pediatric</td>
<td>400+ participants; 35 sites, inc 15 international sites across 6 countries; 3 years; I/C: NHLBI</td>
<td>SIRB; Statistical support; Recruitment and retention; budget planning</td>
<td>05/2020 – Ongoing</td>
<td>Ongoing; submitting October 2020</td>
</tr>
<tr>
<td><strong>Trial Implementation</strong></td>
<td>Preventative medicine</td>
<td>Phase 3; 17,000 participants; 65 sites; 7 years; I/C: NIA</td>
<td>Recruitment and retention plan; Study planning (design, budget, timelines, feasibility)</td>
<td>10/2018 – 09/2019</td>
<td>Funded 10/2019; implemented in the TIN</td>
</tr>
</tbody>
</table>
TIN at our Center

Use of TIN Resources

- Dr. Ron Rodriguez
  - Initial consultation for protocol development
- Dr. Ender Finol (UTSA faculty)
  - sIRB support (JHU)
- Dr. Andrew Meyer
  - sIRB support

Table B.3: IIMS Participation in TIN Trials

<table>
<thead>
<tr>
<th>Proposal Title</th>
<th>Site-PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-IRAD</td>
<td>Neela Patel, MD</td>
</tr>
<tr>
<td>MoTrPAC</td>
<td>Nicolas Musi, MD</td>
</tr>
<tr>
<td>NewIdeas</td>
<td>Arash Salardini, MD</td>
</tr>
<tr>
<td>AWAREII</td>
<td>Elizabeth Scherer, MD</td>
</tr>
<tr>
<td>PREVENTABLE</td>
<td>Sara Espinoza, MD</td>
</tr>
<tr>
<td>MAP</td>
<td>Sara Espinoza, MD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Completed Trials (n=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEAL: DOSE</td>
</tr>
<tr>
<td>ACTIV-1</td>
</tr>
<tr>
<td>ACTIV-6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pending Site Activation or Funding (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHARP</td>
</tr>
<tr>
<td>RNR</td>
</tr>
<tr>
<td>HEAL: SurgeryPal</td>
</tr>
<tr>
<td>Insider</td>
</tr>
<tr>
<td>BEACH</td>
</tr>
<tr>
<td>HEAL: SKOAP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site Selected but Trial Inactivated (n=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRRAMPs</td>
</tr>
<tr>
<td>SHARP</td>
</tr>
<tr>
<td>ValEAR</td>
</tr>
<tr>
<td>MINOCA-BAT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Awaiting Site Selection (n=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTNOW Weaning</td>
</tr>
<tr>
<td>PE-Tract</td>
</tr>
</tbody>
</table>
Addressing roadblocks in clinical trials and accelerating the translation of novel interventions into life-saving therapies
3. TIN Resources in Action

- Consent Builder
- Recruitment and Retention Strategies
- Expressions of Interest
- Single Institutional Review Board
- eConsenting
- Budget justification tool
Dear Shweta Bansal and Karen Nijland:

The Trial Innovation Network is assisting Dr. Leslie Crofford from Vanderbilt University Medical Center (partnering with Meharry Medical College) with their proposal titled: A randomized placebo-controlled, double blind phase 2 clinical trial of memantine for the treatment of cognitive impairment in systemic lupus erythematosus. Clearing lupus fog with memantine - ClearMEMory. A synopsis of the study is attached.

- Therapeutic Area: Autoimmunity
- Funding Source / FDA: Evergreen Therapeutics
- Funding Status: Funded (study funded)
- Expected Number of Sites: 5
- Number of Sites yet to be identified: 4
- Study Population Size: 60

In addition to the standard criteria needed for sites to qualify for participation, this study also requires the following qualifications:

1. Clinical or research space for conducting study visits that include cognitive testing, blood draws, and physical examination
2. Trained clinical or research staff to conduct cognitive testing. Study team will provide training.
3. Clinical or research staff to conduct patient pre-screening and schedule study visits

Sites are being contacted on behalf of Dr. Leslie Crofford with an opportunity to express interest in becoming a potential study site. This Expression of Interest request includes the following pieces: Budget, Protocol, Identify interested PI. Please complete any item(s) in the table below that shows a status of 'not started'. Descriptions of each possible item is outlined below the table. If your site wishes to 'opt out' of this opportunity, you may click on any survey link in the table to indicate this decision. The decision to 'opt out' needs to be entered in only one of the surveys.

<table>
<thead>
<tr>
<th>ACTION</th>
<th>SURVEY LINK</th>
<th>DUE</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHRI-based Cohort Assessment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Protocol Review/Feasibility</td>
<td>-</td>
<td>Protocol Survey Link</td>
<td>2022-08-26</td>
</tr>
<tr>
<td>Budget Review/Feasibility</td>
<td>-</td>
<td>Budget Survey Link</td>
<td>2022-08-26</td>
</tr>
<tr>
<td>Site PI Identification</td>
<td>-</td>
<td>PI Identification Survey Link</td>
<td>2022-08-26</td>
</tr>
</tbody>
</table>

If you, as the CTSA POC, wish to send all or part of this EOI request to an Affiliate site, please click on this link and select from the options provided here: 
Send to Affiliate Link
4. TIN Submission Process

- Submit for local CTSA resources
- Connect with local CTSA TIN Liaison Team
- Discuss your proposal’s fit with the CTSA leadership
- Complete the TIN on-line application: trialinnovationnetwork.org
What Makes a Good TIN Submission?

- A **multi-site** clinical trial design (3+ institutions)
- Interest in **collaborating** with the TIN, **aligning** with its mission
- Potential to demonstrate an **innovative** operational approach
- Opportunity to foster **collaboration** across the CTSA and NIH ICs
- Includes **all populations** affected by the health condition being studied
- **Time** to react to support prior to grant submission
  - 60+ days to 180+ days, dependent on level of support needed
TIN Submission and Consultation

Seek local CTSA support

Submit through the TIN website

TIC/RIC Assigned
- Utah TIC
- JHU-Tufts TIC
- Duke-Vanderbilt TIC
- Vanderbilt RIC

Initial Consultation
Consult with experts who will provide requested support during,
- Kick off call, and
- Topic specific discussions, as needed

TIN review and vote: 3 possible outcomes

- No further support
- Approved for resources
- Approved for comprehensive consultation

Begin discussions/implementation of the resources approved

Assist with getting the proposal ready for submission

Proposal is submitted to funders

Trial Implementation

~30 days

~120-180 days
5. The TIN at Work

400 Total Proposals Submitted

77 Therapeutic Areas Represented

60 CTSAs Submitted Proposals

20 NIH Institutes and Centers Engaged

Last update January 25, 2022
6. Engaging the TIN…

• Helps to streamline the multi-center study process
• Leverages national support along with local hub resources
• Reduces the time required to develop a multi-center study
• Connects investigators with relevant experts
• Works in partnership with other NIH Institutes and Centers
• Provides a competitive funding advantage
Thank you!

- For more information on the TIN visit: www.trialinnovationnetwork.org
- Or contact: bansals3@uthscsa.edu
Learning Objectives:

- Examine informed consent changes
- Discuss changes to institutional forms
- Learn how to apply these changes to your research study
- Provide tips on responding to sponsors/auditors
Why are the forms changing?

- Feedback from research community
- Collaboration with Institutional Compliance & Legal Services
- Ensure compliance with regulatory requirements
- Reduce researcher burden
<table>
<thead>
<tr>
<th>Section</th>
<th>Change</th>
<th>Rationale for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information about Study Participants – “Who is participating in this research?”</td>
<td>Participants on active duty will have the option of having their Command notified by the Research Staff to ensure active-duty Service Members are afforded the time to participate in the study.</td>
<td>Clarified requirements for enrolling DoD participants</td>
</tr>
<tr>
<td>Return of Research Test Results for Genetic Tests to Subjects</td>
<td>Please notify me of findings obtained from this research which (initial one of the four options below):</td>
<td>Added language for clarity.</td>
</tr>
<tr>
<td>Information about Optional Procedures – “What are other research activities that may be done but are not required for your participation?”</td>
<td>Deleted Email Authorization Agreement and Texting language.</td>
<td>No longer an institutional requirement.</td>
</tr>
<tr>
<td>Risks – “What are the risks of participation in the research?”</td>
<td>I UNDERSTAND AND AGREE THAT I MAY BE REQUIRED TO SIGN A RELEASE AND WAIVER WITH THE [insert name of facility] (“PREMISES”) WHERE THE RESEARCH ACTIVITY WILL TAKE PLACE. UT HEALTH SAN ANTONIO DOES NOT OWN, OPERATE, CONTROL, OR MAINTAIN ANY OF THE PREMISES WHERE THE RESEARCH ACTIVITY PERFORMED FOR THE STUDY SHALL TAKE PLACE. UT HEALTH SAN ANTONIO HAS NO LEGAL AUTHORITY TO DIRECT THE PREMISES AND UT HEALTH SAN ANTONIO AND THE PREMISES ARE SEPARATE LEGAL ENTITIES.</td>
<td>Clarified language when some of the study-specific procedures occur offsite (e.g., exercise at a community center).</td>
</tr>
<tr>
<td>Payments – Will there be any payments for participation?</td>
<td>Deleted language regarding subject’s willingness to receive study-related messages.</td>
<td>To be consistent with removal of texting requirements.</td>
</tr>
</tbody>
</table>
## Changes to Informed Consent

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Payments – Will there be any payments for participation?</td>
<td><strong>Active duty</strong> participants are eligible for compensation only if completion of the assessment appointment does not conflict with your military duties.</td>
<td>Clarified requirements for enrolling DoD participants</td>
</tr>
</tbody>
</table>
| Confidentiality – How will your records be kept confidential? | **What is Protected Health Information (PHI)?**  
...contact information such as your name, phone number, and/or email address.  
**How will your PHI be shared?**  
• University approved texting platform. | Expanded to include more examples of PHI.  
Added language to coincide with changes to emailing and texting. |
| Research Consent & Authorization Signature Section | Removed institutional requirements for witness unless required by IRB or Sponsor.  
**Witness still required when using the Short Form.** | No longer an institutional requirement and to be consistent with federal human subjects regulations. |
# Changes to Informed Consent

<table>
<thead>
<tr>
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<th>Change</th>
<th>Rationale for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How you may be contacted throughout the Study.</strong></td>
<td>E-mail Authorization Agreement</td>
<td>Added new section to describe how research teams may communicate with subjects.</td>
</tr>
<tr>
<td></td>
<td>The research team would like to communicate with you regarding your research visits via email, which uses an “encrypted” method for secure transmission. When one of the research team sends you an email, you will receive an email that says “[SECURE MESSAGE]” from a research team member with a link to open the message. When you click on the link it will take you to a secure website where you can read the message and reply after successful authentication. If you are not able to receive email, you may not be eligible to participate in the study.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Texting</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The research team would like to communicate with you regarding your participation via text message. These messages may include information related to your participation in the study and payment information, if applicable. In order to do this, we will share your name and phone number with UT Health San Antonio's secure texting platforms. Standard text messaging rates will apply if you do choose to receive the text messages. If you are not able to receive texts, you may not be eligible to participate in the study.</td>
<td></td>
</tr>
</tbody>
</table>
Changes to Forms, Guidance and Policies

Impacts the following forms:

- Forms D and D-1
- Forms D-IS
- Forms D-PP and D-1 PP
- Form D-Withdrawal
- Forms E and E-1
- Form H-UT
- Informed Consent Policy
- Obtaining Informed Consent – IRB SOP
- IRB Related Questions FAQ
- Institutional Profile
- Institutional Boilerplate Language (for External IRB studies)
# Changes to Institutional Forms

<table>
<thead>
<tr>
<th>Section</th>
<th>Change</th>
<th>Rationale for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor changes throughout forms.</strong></td>
<td><strong>Moved questions around so researchers submitting exempt or expedited projects, do not have to scroll to bottom of form.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Item 3:</strong> Does the research fall under the purview of any other departments, committees, or agencies?</td>
<td>Added Family Educational Rights and Privacy Act (FERPA)</td>
<td>Consistency with regulatory requirements.</td>
</tr>
<tr>
<td></td>
<td>Added NIH Data Management and Sharing (DMS) Policy</td>
<td>Consistent with new NIH requirements.</td>
</tr>
<tr>
<td><strong>Item 4a:</strong> UTHSA or total for all local affiliates</td>
<td>Number of subjects (or records, samples, images, etc.) to be screened for eligibility:</td>
<td>Clarified information that should be entered in this section.</td>
</tr>
<tr>
<td><strong>Item 14:</strong> Sharing of Research Data/Specimens to Entities Outside the Affiliated Study Sites</td>
<td>Allows researcher to submit the NIH DMS Plan instead of completing the table.</td>
<td>Consistent with new NIH requirements.</td>
</tr>
<tr>
<td><strong>Item 15:</strong> Use of electronic study tools to collect, store and/or share identifiable data</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Item 25:</strong> Does the study plan dictate the use of any of the following (whether standard of care or investigational)?</td>
<td>A dietary supplement or substance generally recognized as safe (GRAS)</td>
<td>Clarified wording.</td>
</tr>
</tbody>
</table>
Changes to Institutional Forms

Impacts the following forms:

• Institutional Form
• Institutional CT Form
Applying Changes to your Research Study

Existing Studies – IRB approved prior to 2/23/23

- Check your IRB determination letter.
- Continue to use your IRB approved consent.
- No longer need to obtain witness signature, email authorization or texting choice.
- Remain flexible and always honor wishes of participant.
- At time of next amendment, submit changes to consent.

New Studies – IRB approved after 2/23/23

- Consent form will not include a witness line. Will include revised email authorization and texting language.
- IRB can determine that a witness is required. Will be documented in your IRB determination letter.

Studies in the IRB Queue for Review (Amendments and New Studies)

- IRB team will revise your consent to be consistent with the revised changes.
Applying Changes to your Research Study

External IRB Studies
- Witness signature no longer required by the institution.
- External IRB may require a witness.

Documenting the Consent Process
- Continue to summarize the consent process in the medical or research record.
- Utilize standardized language and consent checklists to ensure process is documented consistently and appropriately.
Responding to Sponsors/CROs & Auditors

Refer Sponsor/CRO or auditing entity to the updated IRB-approved policy, SOP, consent templates and FAQ Sheet.

- IRB Informed Consent Policy and Procedure (revised 02/23/2023)
- IRB SOP on Obtaining Informed Consent (revised 02/23/23)
- IRB approved consent templates (Forms D, D-1, DIS, D-PP, D-1 PP, D-Withdrawal, E and E-1)
- IRB Frequently Asked Questions (revised 02/23/2023)
When will the Forms be Available?

- Changes are effective February 23, 2023.
- Revised forms, SOPs and policies will be available on Monday, February 27, 2023.
Office of the Institutional Review Board (IRB)

Wanda Quezada
IRB Director

Jeannette Watterson
Associate IRB Director

Stephanie Reyes
Regulatory Reviewer

Rebecca Rivera
Research Compliance Coordinator – Senior

Cecilia Hinojosa
Research Compliance Coordinator – Senior

Stephanie Perez
Research Compliance Coordinator
Office of Clinical Research (OCR)

Brandie Otten
Research Compliance Manager

Patricia Alexander
Research Compliance Coordinator - Sr

Alyssa Hernandez
Research Compliance Coordinator

Bhumi Patel
Research Compliance Specialist

Stephen B. Luis
Research Compliance Specialist

Angelika Malolos
Research Compliance Specialist
How may we assist you?

Concierge appointments are now “On Demand”

Register online for virtual concierge:
https://redcap.uthscsa.edu/REDCap/surveys/?s=4TKCEP74J347ML83

Thank you for attending the Research Forum
A Big Thank You!

Jeannette Watterson

Brandie Otten

Angelife Pardo

Melissa Bazan

Matt Grove
Questions?