Clinical Research Units and Clinical Trials –IRB workgroups

Topic 1: Master Trials Agreements (MTAs)

- We have a number of MTAs with Industry sponsors for implementation throughout the entire UT System.
- We need to accumulate more MTAs and develop some with commonly utilized CROs.

Action Item: Beth-Lynn Maxwell will solicit list from 4 CTSAs of the most commonly needed MTAs, and CTSA-CRUs will convey to UT System Legal Office, the greatest needs for MTAs with CROs. Deadline = 6 months.

Topic 2: Agreements with non-CTSA Affiliates

- Various clinical partners of each CTSA may have other regulatory and approval processes beyond the IRB.
- These approvals add to the burden and timeline for regulatory approval to begin study.
- However, this problem is CTSA site-specific and beyond the scope of UT System or CT Express.

Action Item: Each CRU or Regulatory group at each CTSA will determine what processes can be improved to aid their investigators so as to enhance the TRCC network capacity for study implementation at those clinical partners and affiliates. Deadline = 12 months

Topic 3: Enhancing Use of Central IRBs

- Most CTSAs do have or have had agreements with WIRB or other commercial IRBs. Some do have and we agree that all need agreements with IRB-Rely as an official NIH central IRB.
- We agree that more central agreements with more central IRBs will help the TRCC to engage multisite trials nationally.

Action Item: Regulatory Leaders at each of the 4 CTSAs will communicate with Beth Lynn's office a list of core IRBs to formulate master agreements with them. Deadline = 6 months

Topic 4: Facilitating Other Institutional Approvals for Multisite Trials

- There are other institutional approvals beyond IRB (i.e., HR, IT, Credentialing, coverage analysis, scope of practice, etc.), that investigators must achieve in order to implement studies.

- In order for investigators and staff from various UT System institutions to collaborate together and possibly share or access cross institutional resources, there needs to be cross-institutional approvals for personnel working across institutions.

Action Item: CRU groups from each of the CTSAs will share best practices and will be the point-of-contact to assist cross-institutional investigators and staff with gaining the local approvals necessary. Deadline = CRUs points of contact are established, future discussion may yield plan to address larger system issues.

Topic 5: Identifying Pools of Investigators and Pools of Patient Populations for TRCC trials

- We compiled lists – but these are difficult to maintain
- Use of Sci-Val and Influent is not perceived as helpful to identify a new investigator
- Discussed the use of NCBI Pub Med Central as an active, well maintained data source.

Action Item: The navigator at each CTSA site should be charged with knowing who the potential investigators and patient clinics may be for proposed new trials. Navigators, coupled with the CRU Manager(s) at each CTSA site, should be the points of contact to identify investigators and patient pools needed for CT-Xpress and other multisite trial queries. Deadline = 12 months

Topic 6: Initiate a multisite trial through the TRCC as a proof of concept.

- There are now three such trials (Abate, Tyson, and Arain) operating within the TRCC

Mission accomplished, No Action Required – other than recruit more trials

Topic 7: Standardize Trials Metrics as implemented through Velos

- Each institution is implementing a local instance of Velos and largely but not completely implementing standardized metrics
- CT Xpress is generally adopting some of these standardized metrics for monitoring trials progress
- CTSA national consortium is still evolving the standardized metrics they expect hubs to use and report on for a system-wide implementation

Action Item: Get Velos fully implemented at each site. Insure that CT Xpress is using metrics and able to track trials progress effectively. Deadline = 12 months

Topic 8: How to implement Central IRB issues within CT-Xpress?

- Currently, the TRCC site initiating the trial serves as the IRB of record or UT-Houston serves that role for TRCC

- But, how will the process work when involving an external central IRB like WIRB?

Action Item: the executive TRCC committee should discuss how this will be handled.
Deadline = 12 months

Topic 9: Should CT-Xpress sign a Master Trial Agreement for all TRCC or is this handled as a UT-System Master Agreement which each participating site endorses?

Action Item: the executive TRCC committee should discuss and Patti Wenger will get with Beth-Lynn Masters on how this will be handled. Deadline = 12 months

Topic 10: Possible sharing of Vendors for Concierge Services

- Each CTSA site variously needs concierge services to support trials such as language translational service, patient transportation (including airplane, bus), and external quality assurance monitoring, etc.

Action Item: CRU Managers will share "Best Practices" to make available UT-approved vendors for these services with the possibility of standardizing the resource or making it more readily accessible. Deadline = 6 months

Topic 11: Sharing Training Resources for Workforce Development as Applies to GCP

- Under the new FOA, each CRU should endorse helping local investigators and staff to train in best practices for Ethical Conduct of Research and Good Clinical Practice (GCP).
- The TRCC could/should share training resources and best practices for such training and assurance of GCP.

Action Item: the CRU Managers at each site will share best practices and seek to identify possible shared training resources. Deadline = 12 months