



TARGIT Collaborative Group

Rules for Required Document Submission to the TCG

1. If a party does NOT require IRB approval

- a. The interested party bears full responsibility in determining whether or not their institution requires local IRB approval beyond the central Western IRB approval already obtain by TCG to conduct the quality collaboration.
 - i. A copy of the approval should be included
- b. If the party does NOT require local IRB approval, then the party must notify the TCG via Mark Leshyk, Coordinator. He in turn provides the following:
 - i. DUA template
 - ii. Data fields
 - iii. TCG (Sponsor) protocol
- c. Their institutional or practice representative will review and sign the DUA agreement. Modest modifications of the DUA may be permitted. Sites will under no circumstances be permitted participation without a completed and signed DUA.

2. If a party DOES require IRB approval

- a. The interested party bears full responsibility in determining whether or not their institution requires local IRB approval, or IRB approval in general.
- b. If the party DOES require IRB approval, then the next step is for that party to determine, independently of the TCG, how to proceed.
 - i. The party must then either:
 1. Obtain local institutional IRB approval
 2. If they lack their own, proceed with Western IRB or similar central IRB and acquire subsequent approval
 - ii. The party will complete, without any responsibility or burden placed upon the TCG, their IRB aspects as appropriate.
 1. The party **MUST PROVIDE** to TCG proof of IRB approval after it has been obtained.
- c. For those parties that DO require IRB approval, regardless of which IRB the request is processed through:
 - i. TCG Coordinator, Mark Leshyk, will provide the party, upon request and notification that IRB approval is required, with the following:

1. An IRB approval template based on IRB submission completed by Mr. Leshyk for his local institution, Loyola University Chicago Medical Center (LUMC).
 - a. The documents attached as a template will include:
 - i. Loyola-specific protocol
 - ii. TCG (sponsor) protocol
 - iii. Data Fields
 - iv. DUA template
 1. Their legal team will work on their own DUA agreement. Sites will under no circumstances be permitted participation without a completed and signed DUA.