

## Role of the Office:

By integrating existing ICTR resources and personnel, the TIU supports:

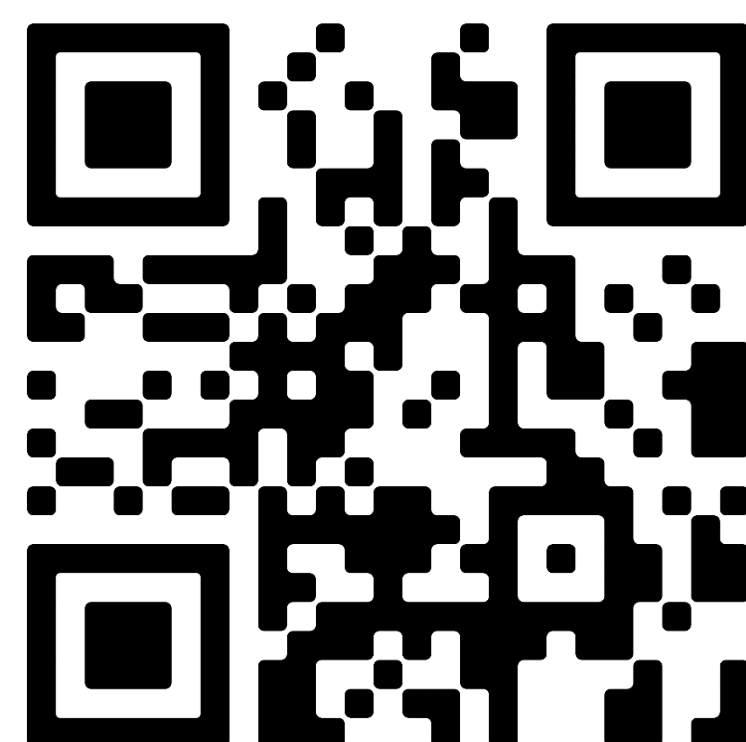
- Single-site trials with potential for multicenter expansion
- Multicenter trials being prepared for Trial Innovation Network (TIN) submission
- TIN-assigned multicenter trials
- Investigators with underdeveloped protocols interested in TIN support

The TIU is supported by the Division of Brain Injury Outcomes (BIOS), a JHU-based academic research organization with experience in developing and supporting commercial and non-commercial clinical trials. Led by Daniel Hanley, MD, BIOS has unique expertise in the coordination and management of trials across all areas of human subject research.

The TIU is committed to facilitating the development of investigative expertise. K-grant, T-grant, and other early career investigators are invited to participate in project evaluation, trial simulation, and planning activities. Biostatistical doctoral and postdoctoral candidates may participate in statistical analysis plan development and reporting.

# Trial Innovation Unit (TIU)

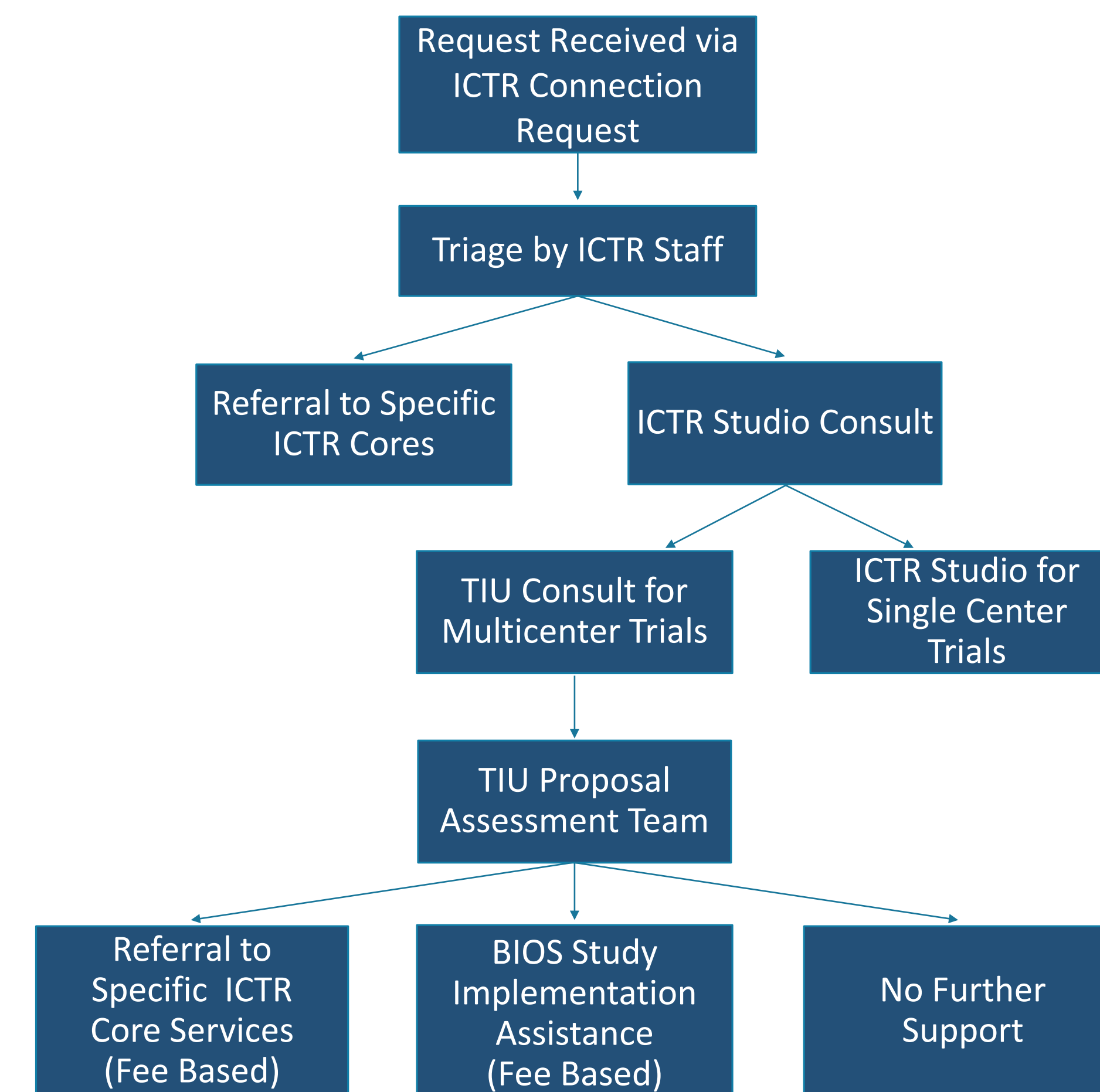
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- The Trial Innovation Unit leverages Trial Innovation Network practices to help investigators conduct innovative multicenter clinical trials.
- Investigators may request a TIU consult during the grant planning (pre-funding) or grant implementation (funded) stages.
- Single IRB is a requirement for all NIH-funded multicenter clinical trials.

## Services Provided:

### TIU Process: Multicenter Trials



### BIOS Services (fee based)

- Grant writing assistance
- Protocol development and refinement
- sIRB (single IRB) coordination and reliance agreements (SMART IRB)
- Cohort discovery and site selection assistance
- Budget planning
- DSMB charter development
- Biostatistics planning and analysis
- Comprehensive risk assessment
- Recruitment and retention plan
- Database design and management
- Accelerated project start-up
- Clinical project management