Process for IRB Approval for the FASTEST Trial

1) Register in the Advarra Center for IRB Intelligence (CIRBI - cirbi.net) (if you do not already have an account)
    - Click here to register for an account
        - Anyone who needs to be added to the application will need an account. The link above can be used to register on behalf of someone else, if needed.

2) The following two steps can be done in parallel:
    - Develop a site-specific EFIC plan (please reference the *Memorandum and Guidance on EFIC Activities for the FASTEST Trial* and the *FASTEST: Model EFIC Proposal*)
        - The NIH StrokeNet National Coordinating Center (NCC) must review and sign off on the plan prior to submission to Advarra.
    - Complete the "Investigator Application" in CIRBI (after "Login", the button to begin the application is located in the vertical menu to the left) (within the application, please reference "Protocol Number:" 03496883 (FASTEST))
        - Once the site-specific EFIC plan has been signed off by the NCC, it can be uploaded into CIRBI and the application can be submitted.

3) Once the application has been submitted, Advarra will pre-review the proposed site-specific EFIC plan and provide feedback on the plan through CIRBI. A response to the feedback is not required at this time, however, it is strongly recommended that any suggestions or recommendations by Advarra are incorporated into the plan before execution. The application will move into a deferred state until the plan is fully executed.

4) After the EFIC plan is fully executed and the data is compiled, upload a report and respond to Advarra's pre-review feedback through CIRBI.
    - The NCC must review and sign off on the report prior to submission to Advarra.

5) Once the report and pre-review feedback responses are submitted, Advarra will review the full application and communicate its approval decision through CIRBI.
    - When approved, approval documents will be available in CIRBI.

There are protocol-level community-facing materials available for use (only contact information can be added, no changes in content can be made). Given the IRB approval process, if there is a need for any additional community-facing material, a request can be made to the NCC, as the material would have to be submitted and approved at the protocol-level.

For questions, please contact FASTEST Trial leadership, the NCC, or Advarra:
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