The Medical Center, Navicent Health
Items Needed to Submit Protocol to IRB:

1. One (1) Actual protocol.

2. FDA 1572 (or Statement of Investigator) signed. If you are using the FDA 1572 send copy, if you are using the Statement of Investigator send the original.

3. CVs for all listed on FDA 1572 (or Statement of Investigator).

4. Investigator's Brochure.

5. One (1) ORIGINAL Application.

6. One (1) ORIGINAL Consent Form.

7. Items 1-6 are to be kept separate from #8.

8. 15 sets of the application and consent form (this does not include the originals as stated in #5 and 6 above). These can be stapled together (one application and one consent form, etc.).

9. Copy of current certification of competency to perform research on human subjects, if not already on file.

10. Applicable submission fee (see fee schedule below)

11. The above items **MUST** be submitted at least two weeks **PRIOR** to the monthly meetings.

12. The principal investigator shall be present at the IRB meeting to present the proposal in sufficient detail to permit adequate consideration.

IRB Fee Schedule, Effective July 1, 2002:

New Protocol Review: includes initial review, amendments, SAE, and other reports during the first year. • $1000 for New Protocol Review -- Industry or other State/National/International funding • $250 for New Protocol review -- locally (non-industrial) funded trials and non-funded trials
Expedited Reviews: • $500 -- Any Expedited Review -- for new protocols, the above initial review fees will be added.
Annual Renewal Reviews: includes review of renewal data, amendments, SAE, and other reports for the next year. • $500 -- Annual Renewal -- Industry or other State/National/International funding • $100 -- Annual Renewal -- locally (non-industrial) funded trials and non-funded trials
Note: If the proposed study has a **not-for-profit sponsor or if there are special circumstances for consideration,** you may request a reduction or waiver of fees.

Protocols approved prior to July 1, 2002 will remain exempt from fees.

08/01/19