

Instructions for Submitting and Completing the Application for IRB Review

1. Submission Requirements:

In order to demonstrate appropriate oversight of human research activities and to comply with federal regulations, state statutes, and applicable policies and procedures, no human subjects research activities can be initiated prior to obtaining TMMC IRB review and approval.

Prior to submitting your proposed study to the IRB, please use the following guideline to determine if it is Research or Quality Improvement (QI)/Performance Improvement:

RESEARCH VERSUS QUALITY IMPROVEMENT (QI)/PERFORMANCE IMPROVEMENT (PI) GUIDE AND CHECKLIST

***Torrance Memorial Medical Center ONLY Participates in research for Adults.
Subjects must be 18 years of age or older.**

CHECKLIST:

- Application Fee of \$1500 for a funded study

FOR ALL INITIAL REVIEW REQUESTS, please provide 7 copies:

- Application for Research Project/Study
- Principal Investigator's Current Curriculum Vitae (CV), signed and dated.
- Principal Investigator's Current Professional License
- Consent Form
- HIPAA Form
- Protocol
- Project Summary
- Recruitment/Advertisement Materials
- Conflict of Interest Disclosure Form
(For PI(s), all Co-Investigators and all study personnel)
- Evidence of Training in Human Subject Protections
(For PI(s) and anyone else authorized to obtain consent)

FOR STUDIES OF DRUGS OR BIOLOGICS

- Investigator's Brochure (3 copies)
- IND Safety reports, drug inserts, or other documents relating to the study agent
- FDA Form 1572, signed and dated, OR if an IND has not been filed, then an explanation as to why it was not filed